EPIDEMIOLOGY, DIAGNOSIS, AND CARE-SEEKING RELATED TO RISK FACTORS FOR INTRAPARTUM-RELATED FETAL AND NEONATAL DEATH IN RURAL NEPAL

by
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Abstract

Intrapartum-related complications are the second leading cause of neonatal death. To better target this cause, this thesis examines the epidemiology of intrapartum-related mortality and morbidity in rural Nepal, and assesses the feasibility of community-based antenatal diagnosis of risk factors for intrapartum-related complications, including non-cephalic presentation, multiple gestation, and placenta previa.

The research was nested in the Nepal Oil Massage Study, conducted in rural Sarlahi District, Nepal. The research consisted of several components: 1) a community-based prospective cohort study to examine the incidence of third-trimester obstetric risk factors and their associations with adverse pregnancy outcomes, 2) a community-based cross-sectional survey to understand the awareness and utilization of obstetric ultrasonography in the study area, 3) a community-based validation study to examine how accurately lower-level health workers with limited training can use portable ultrasound to detect three major risk factors of adverse intrapartum-related pregnancy outcomes: non-cephalic position, multiple gestation, and poor placental position / placenta previa, 4) in-depth interviews with mothers who recently experienced a non-cephalic birth and/or female decision-makers in their household to discuss their care-seeking behavior and risk perception toward non-cephalic presentation, and 5) focus groups with women in the community pertaining to the same topic.

We observed a very high risk of adverse intrapartum-related outcomes associated with non-cephalic and multiple birth respectively. Many women who experienced these conditions were undiagnosed prior to delivery. Only about a quarter of the women in our

community received an obstetric ultrasound exam during their most recent pregnancy. Lower-level health workers with limited training were able to diagnose non-cephalic position and multiple gestation with high validity using ultrasonography. Despite the very high adverse outcome rate among non-cephalic births, the perceived risk of the condition varied widely.

Fetal and neonatal mortality and morbidity attributable to intrapartum-related complications have fallen at a much slower pace than those attributable to other causes. We highlighted here the potential for targeting low-prevalence, but high-risk obstetric risk factors to reduce the health burden in low-resource settings caused by intrapartum-related complications.

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Table of Contents

List of Tables

Chapter 1: Introduction

The 2014 Lancet Every Newborn series proposed national neonatal health targets for the year 2035: no more than 10 stillbirths per 1000 total births and no more than 10 neonatal deaths per 1000 live births.[1] The series highlighted the time of birth as having the highest return on investment; it attributed 46% of maternal deaths and 40% of neonatal deaths and stillbirths to the intrapartum period and the birth day.[1] Estimated 45% and 75% of intrapartum stillbirths could be averted if all women deliver at basic emergency obstetric care (BEmOC) or comprehensive emergency obstetric care (CEmOC) facilities respectively.[2] Severe morbidities can also occur due to complications during labor and delivery. Among the 1.2 million newborns who develop neonatal encephalopathy due to intrapartum-related complications, 287,000 die and over 400,000 go on to live with neurocognitive or motor impairment.[3] These measures of mortality and morbidity also do not take into account the less quantifiable psychological impact of fetal or neonatal loss on the mother.[4]

This dissertation explores the epidemiology of intrapartum-related mortality and morbidity in rural Sarlahi District, Nepal, and assesses the feasibility of community-based, antenatal diagnosis of obstetric risk factors (non-cephalic position, multiple gestation, and placenta previa) for intrapartum-related complications using ultrasonography. In an area like Sarlahi District where coverage of antenatal care and ultrasound access are low, we assume very few women are diagnosed with risk factors prior to the start of labor. Furthermore, many women face social, economic, and cultural barriers to seeking care at facilities that are equipped to handle obstetric risk factors.

Early diagnosis may help remove some of those barriers and shorten delays in care-seeking. Findings from this dissertation will contribute to the dialogue on antenatal maternal risk screening to prevent intrapartum-related mortality and morbidity.[1] Targeting intrapartum-related complications is now especially relevant in low- and middle-income countries (LMIC) like Nepal, with neonatal mortality due to this cause declining slower than those attributable to other major causes.

Background

Intrapartum-related mortality and morbidity

Stillbirth is defined as a fetal death occurring in the third trimester, with birth weight greater than or equal to 1000g or with more than 28 completed weeks of gestation. An estimated 2.6 million stillbirths occur each year, with 98% of them occurring in LMICs.[5] Stillbirth has been largely neglected as a major health issue; the rate of decline of stillbirths in low-resource settings was only 0.6% between 2000 and 2009.[6] The rate of decline is slower than observed in under-five mortality (2.3% decrease per year).[5] Stillbirths can be categorized into two groups: intrapartum (or fresh), which are associated with obstetric emergencies and are assumed to have occurred within the 12 hours prior to delivery, and antepartum (macerated), which are associated with maternal infections and intrauterine growth restriction and occur prior to labor and delivery.[7] Stillbirths can be differentiated using external signs; the extent of desquamation or peeling of the skin (severity, surface area, location of the desquamation on the body), skin color, and mummification are all good indicators to identify whether stillbirths

occurred earlier than 12 hours before delivery.[8] A little less than half of the estimated stillbirths are attributable to intrapartum causes (1.2 million).[9] Lawn et al. highlight that the percentage of stillbirths attributable to intrapartum causes is higher in low-resource settings such as South Asia and sub-Saharan Africa.[9]

Neonatal mortality is defined as death in the first 28 days of life. Worldwide, an estimated 2.7 million neonatal deaths occur annually.[10] Preterm birth, intrapartum-related complications, and sepsis/meningitis are the three leading causes of neonatal mortality for year 2013 estimates.[10] Newborn conditions account for 8.1% of global disability-adjusted life years.[11] There have been great strides made in protecting neonatal health over recent years. The total estimated number of neonatal deaths decreased by 400,000 between 2010 and 2013, with reductions in intrapartum-related death accounting for 55,000 of them.[12] Much of this reduction is attributable to new interventions that have been researched and tested over the last few decades. Several interventions included in the Lives Saved Tool model, a software tool that estimates the impact of evidence-based interventions on country-level mortality estimates, are application of antiseptics on the umbilical cord for prevention of sepsis mortality, antibiotic provision for treatment of sepsis and pneumonia, and Kangaroo mother care / hypothermia prevention for preterm infants.[13]

Stillbirths and early neonatal mortality (death within the first week of life) share several etiologies, such as maternal infections,[14] maternal hypertensive disorders,[15] smoking,[16] and fetal congenital abnormalities.[17] However, the main shared etiological factor is intrapartum-related events (previously known as birth asphyxia); it is estimated to be the direct cause of roughly half of fresh stillbirths and early neonatal deaths.[9]

Intrapartum-related complications that can cause hypoxia include the following: restricted blood flow due to complications such as pre-eclampsia/eclampsia and compression of the umbilical cord, placental abruption, restriction of fetal oxygen due to prolonged labor, and fetal entrapment due to fetal malpresentation.[18] Estimates for the year 2013 reported 660,000 (95% CI: 421,000-1,054,000) neonatal deaths attributable to intrapartum-related complications,[10] and a recent conference presentation reported an estimate of approximately one million stillbirths attributable to intrapartum-related causes.[19] These intrapartum-related hypoxic events are also associated with long-term morbidity. If primary or secondary prevention of hypoxia is not successful, newborns can suffer from neonatal encephalopathy, and as a consequence, experience cerebral palsy or other neurocognitive and motor impairments.[3] Lee et al. estimated that in 2010, 1.15 million neonates experienced neonatal encephalopathy associated with intrapartum-events. Of those, 287,000 died, 233,000 had moderate or severe neuro-developmental impairment, and 181,000 had mild impairment.[3]

Much of the aforementioned mortality and morbidities are preventable with skilled attendance at labor and with use of basic equipment. Providing appropriate obstetric care during labor and delivery has the potential to reduce neonatal deaths and stillbirths by 41% and 70% respectively.[13] Vaginal delivery of potentially complicated deliveries such as fetal malpresentation or multiple gestation may be possible with skilled birth attendance, but are best conducted in CEmOC facilities that can conduct cesarean section (C-section) if necessary. In any population, C-section rates should be around 15% based on the expected prevalence of obstetric complications requiring C-section,[20] but are

as low as 5% in rural South Asia and near 0% in rural Sub-Saharan Africa.[9] One review estimated that for a one-percent increase in C-section rates in a country (up to 8%), stillbirth rates drop by approximately 1.6 stillbirths per 1000 births.[21] Another analysis using World Health Organization (WHO) data also reported proportional reductions in stillbirths with increase in C-section rates, but only up to a C-section rate of 10%.[22]

Risk factors for intrapartum-related complications

In the late 1980s, the maternal health community explored the concept of antenatal risk screening to reduce intrapartum-related mortality.[23] However, many of the risk factors that were examined at the time were high in prevalence (i.e. primparity, short stature, young maternal age); the sensitivity of these risk factors in detecting complications or mortality/morbidity was high, however the positive predictive value was low.[24] Other studies have explored risk factors for intrapartum-related deaths with lower prevalence, high sensitivity, and high positive predictive value, such as non-cephalic presentation / fetal malpresentation, multiple gestation, and vaginal bleeding (as an indicator for placental issues, such as placenta previa and placental abruption).[24-26]

Non-cephalic births. Non-cephalic births are defined as births where the fetus presents first with a body part other than the head. At around 28 weeks in gestation, 20% of fetuses are in a non-cephalic position, and by term, the prevalence drops to around 3-4%.[27] A U.S.-based study reported a prevalence of 10-11% at 32-33 weeks of age, which then dropped to 3.7% at 37-40 weeks.[28] Non-cephalic presentation includes several positions. Breech describes positions where the lower extremities are situated downward.

Frank breech is when the lower half of the fetus is flexed at the hip, with the knees extended (feet around the face), complete breech is a similar position but with the knees bent, and incomplete breech is one or both feet or knees are situated below the hip. Transverse position is when the fetus is situated horizontally across the mother. While gestational age is correlated with the prevalence of non-cephalic positioning, other risk factors such as multiple gestation, placenta previa, hydrocephaly, and anencephaly may predispose fetuses to non-cephalic presentation.[29]

Detection and management of breech (using C-section) was one of the 16 interventions identified in the 2005 Lancet Neonatal Series to reduce neonatal mortality rates.[30] While C-section rates are being tracked in most Health Management Information Systems (most recent data from 57 Countdown to 2015 countries reporting 5.9% (IQR: 3.4-8.8)), prevalence and outcomes of non-cephalic births are not reported systematically at this time.[6] Non-cephalic fetuses can be delivered vaginally by appropriately trained staff, depending on the exact fetal position. In the U.S., the American Congress of Obstetricians and Gynecologists (ACOG) recommends that the decision to deliver the breech fetus vaginally or by C-section depend on the training of the provider.[31] The expectation is that most fetuses will be delivered by C-section due to fewer physicians being trained to perform vaginal breech delivery than in the past in the U.S.[31] There is a concern that the volume of non-cephalic births is too low to adequately train residents to deliver the fetus vaginally.[32] In 2003, the U.S. national average C-section rate among breech births was 85.1%.[33] Certain types of non-cephalic presentation are indicated for C-section regardless of health personnel training. For instance, approximately 5% of term

breech fetuses have their heads in a hyperextended position.[29] Delivering those fetuses vaginally could injure the cervical spinal cord.[29] In its training manual for midwives, the WHO states that if the fetus is in transverse lie or other obvious malpresentation within one month of expected delivery, mothers should be instructed to deliver at a referral-level facility.[34] In Tanzania, abnormal presentation of the fetus qualifies for emergency intrapartum referral as a policy of the Ministry of Health.[35]

There is literature from high- and middle-income settings suggesting a reduction in adverse outcomes among term breech births if they are delivered by C-section rather than vaginally.[36-38] In the multi-center Term Breech Trial, the frequency of perinatal mortality, neonatal mortality, or serious neonatal morbidity was statistically significantly lower in the planned C-section group (RR 0.33, 95% CI: 0.19-0.56).[36] However, it should be noted that these trials were conducted in contexts where safe, high-quality C-sections were available. While there are reports of vaginal breech deliveries occurring with minimal perinatal consequences,[39,40] ACOG notes that these studies were in contexts where those who had vaginal breech deliveries were carefully pre-screened and selected, with comprehensive protocols in place for handling breech deliveries.[31] While the data are now outdated, a study examined maternity records from hospitals affiliated with Family Health International located around the globe, dating from 1977 to 1982. In that study, the authors reported a neonatal mortality rate of 23.8 per 1000 live births for C-sections and 67.4 per 1000 live births for vaginal deliveries among non-cephalic births, for an unadjusted RR of 2.8 (95% CI: 2.2-3.6). The RR was still significant, but lower

(RR 1.9, 95% CI: 1.3-2.7) when limiting the hospitals to those in high mortality countries (>45.0 perinatal deaths per 1000 births).[41]

Perhaps owing to the high prevalence of home births and a dearth of CEmOC facilities in low-resource settings, along with the low incidence of non-cephalic presentation, there is limited literature on the burden of or care pertaining to non-cephalic births in developing country settings. Lawn et al. reported adjusted odds ratios (aOR) of all-cause neonatal/perinatal deaths, ranging from 6 to 15 for breech, and 8 to 34 for other non-cephalic positioning in LMICs.[42] In a study conducted in 25 public sector sites in Lusaka, Zambia, assisted breech births had an aOR of 7.93 (95% CI: 5.92-10.61) for fresh stillbirth.[43] In a community-based setting in rural Congo, 50% of perinatal deaths occurring in the community were among breech births, despite the fact that the overall incidence of breech births was 2.5%. The aOR for perinatal mortality was 12.41 (95% CI: 4.62-33.33).[44] A West African study reported a statistically significant odds ratio of 8.4 for stillbirths among breech deliveries.[26] A retrospective medical review conducted at the Nepal Medical College reported vaginal breech presentation as a major risk factor for perinatal mortality.[45,46] A study published in 1995 reported perinatal mortality rates of 375.6/1000 births and 183.7/1000 births at two major hospitals in Kathmandu among non-cephalic deliveries.[47] An examination of the zonal hospital in Bheri, Nepal, had a stillbirth rate of 258/1000 births for breech deliveries (year 1997). The authors estimated that only 6.5% of breech babies had access to proper obstetric care.[48] Even fewer studies have reported associations between fetal malpresentation and intrapartum-related morbidities, and they are mainly conducted in hospital settings.[49-51] Non-cephalic

presentation can also be a risk factor for prolapsed cord. Breech delivery is also associated with higher risk of fractures and spinal cord injury for the fetus and genital tract lacerations for the mother.[29]

There are minimal data on cultural perceptions of the etiologies and/or consequences of non-cephalic presentation. An ethnographic study from the 1980s in Nepal's Magar ethnic group reported the cultural association between breech births and maternal and perinatal mortality. Women would attempt to turn a breech baby around in the womb, and if unsuccessful, it was said that the child inside bites the mother's heart, leading to both maternal and fetal death.[52] There are also limited data on current care practices for non-cephalic births. A report by United Nations Population Fund and EngenderHealth reported observations from Chad that if the traditional birth attendant during delivery cannot feel the head of the fetus due to poor positioning, she will hold the woman by the ankles and shake her in the hopes that the fetus will rotate. The report refers to this care behavior as potentially leading to or further complicating prolonged labor and putting the mother at greater risk of obstetric fistula.[53]

Multiple births. Multiple births are also considered a risk factor for intrapartum-related complications. The incidence of twinning is estimated at 13.1 per 1000 pregnancies in developing countries,[54] and ranges from less than 1% in most of Asia to closer to 2% in Western and Central Africa.[54] Multiple births benefit from delivery at referral-level facilities for several reasons. First, obstetric complications are common among twins. Twins can be retained (delivery of the second twin occurring over 30 minutes after the first twin), leading to complications,[55-57] and a large proportion of twins

have at least one twin presenting in non-cephalic position.[56-58] At the University of Nigeria Teaching Hospital, approximately a sixth of the twins delivering at the hospital between 1991 and 2000 had a retained second twin, and the second twin experienced a perinatal mortality rate of 288.5 per 1000 deliveries, 1.7 times higher than the first twin. Malpresentation was the largest contributor (54%) to the retention.[56] Another Nigerian study reported roughly 40% of all twin births having at least one twin presenting in non-cephalic position.[58]

Second, there is high prevalence of intrauterine growth restriction (IUGR) and preterm birth among twins.[59,60] Preterm and intrauterine growth restricted newborns have a significantly higher risk of neonatal mortality; newborns who are both IUGR and preterm have over eight-fold increased risk of neonatal mortality in developing country settings.[61] These newborns also experience long-term morbidity consequences as well, which may partially be avoided with immediate newborn care at a facility.[62,63]

Finally, mothers may be at higher risk of hypertensive disorders by being in a multiple gestation pregnancy. A review reported that women with a multiple gestation pregnancy have increased risk ranging from 1.2-2.7, 2.8-4.4, and 3.4-5.1 for gestational hypertension, preeclampsia, and eclampsia respectively, compared to women with a singleton pregnancy.[64] Pregnancy-induced hypertension, eclampsia, and pre-eclampsia can place both the child and the mother at risk for adverse outcomes.[60,64,65]

Much of the developing country literature on multiple gestation comes from Africa (particularly Nigeria, where twinning rates are high at around 2%) and also from tertiary facilities, which may not necessarily be representative of the population-level

burden.[55-60,65,66] A study in Guinea-Bissau reported a perinatal mortality aRR of 2.71 (95% CI: 1.93-3.80) for twins, with a community-based perinatal mortality rate of 218 per 1000 deliveries and a facility-based perinatal mortality rate of 237 per 1000 deliveries among twins.[59] A Nigerian study reported a maternal mortality ratio of 895 maternal deaths per 100,000 live births and a perinatal mortality rate of 213 deaths per 1000 births associated with twinning.[66] At the zonal hospital in Bheri, Nepal, the stillbirth rate for twin deliveries was 133 per 1000 births (year 1997).[48] Data from the site this dissertation work was conducted at, collected between 1994-1997, reported a twinning rate of 16.1 per 1000 pregnancies, of which over half had at least one stillborn twin.[67] Live-born births had an RR of 8.54 (95% CI: 6.66, 11.00) of early neonatal mortality, compared to singletons.[67]

Placenta previa. Placenta previa is a pregnancy condition where the placenta partially or completely covers the cervix, and is a major risk factor for hemorrhage. Labor and delivery care for placenta previa depends on the extent to which the placenta is covering the cervix. C-section at 36-37 weeks is indicated if the placenta completely covers the cervix, and recommended if the placenta reaches the edge of the internal os. If the placental edge is more than 1-20mm from the cervix, a vaginal delivery may be attempted, with the risk of bleeding becoming greater the closer the placenta is to the internal os. Women with placenta previa, particularly if there is an active bleeding episode, are closely watched on an outpatient basis.[68]

A systematic review reported an overall global prevalence of 5.2 cases per 1000 pregnancies (95% CI: 4.5-5.9), but the prevalence was higher when limited to studies in

Asia (12.2 cases per 1000 pregnancies, 95% CI: 9.5-15.2).[69] Placenta previa has been linked to major obstetric complications, such as antepartum and postpartum hemorrhage, the leading cause of maternal death. A population-based study examining data from Nova Scotia reported statistically significantly increased rates of major anomaly (aOR 2.48, 1.50-4.11) and respiratory distress syndrome (aOR 4.94, 3.45-7.08) among newborns of mothers with placenta previa.[70] A study conducted in a university hospital in Israel also reported increased odds of congenital malformations (OR 2.6, 95% CI: 1.5-4.2), perinatal mortality (OR 2.6, 95% CI: 1.1-5.6), Apgar score less than 7 at five minutes (OR 4.4, 95% CI: 2.3-8.3), and postpartum hemorrhage (OR 3.8, 95% CI: 1.2-10.5).[71] A study from an Ethiopian university hospital reported that of 253 women diagnosed with placenta previa, 113 (44.7%) experienced a stillbirth or early neonatal death.[72]

Health systems and intrapartum-related complications

Data obtained through the Delphi method reported median estimates of 45% and 75% of intrapartum stillbirths averted if all women deliver at BEmOC or CEmOC facilities respectively.[2] However, even if women are antenatally diagnosed with risk factors for intrapartum-related complications, there are many steps between diagnosis and receiving appropriate care. A seminal paper by Thaddeus and Maine highlighted three main factors that influence care-seeking upon a mother experiencing an obstetric complication. Now best known as the "three delays model," they listed the following delays: delay in seeking care, delay in reaching the facility, and delay in receiving appropriate care once arriving at the facility.[73]

Thaddeus and Maine reported that socioeconomic and cultural factors, accessibility of facilities, and quality of care all impact one or more of these delays. Cost is a barrier, both in deciding to seek care and arranging transport to seek care. Several countries have tried to address this issue. In Burkina Faso, antenatal care user fees were removed and all deliveries are now subsidized.[74] As a result, it saw an increase in facility-based deliveries between 2007-2012.[74] They also saw no statistically significant differences in facility delivery rates by wealth quintile.[75] In Nepal, birth preparedness (e.g. saving money, arranging for transport, finding a blood donor) was an important predictor of facility-based deliveries (aOR 3.13, 95% CI: 2.32, 4.23).[76] Nepal also instituted in 2009 a cash transfer system for facility-based deliveries and antenatal care visits, which has been received positively.[77] However, there are some reports of the program disproportionately aiding wealthier families, rather than reaching those in greatest need.[78] The decision to seek care may also not be in the hands of the pregnant woman. Parkhurst et al. report that local healers and traditional birth attendants served major roles in Bangladesh, while in Uganda, husbands played the largest role in the decision on when and from whom to seek care for labor and delivery.[79] Perceptions of severity of a health condition can also affect the decision to seek care.[73,80-82] A qualitative study in Kenya reported that a previous history of uncomplicated deliveries served as a deterrent to seek care.[83] Perceived quality of facility care also affects care-seeking decisions.[83-85] Thaddeus and Maine reported that quality of care is a higher priority compared to cost among the studies they reviewed.[73] It is also important to note the potential for complex interactions among these predictors of care-seeking. For instance, a qualitative study conducted in

Bangladesh and Uganda noted that cost and transport were cited as barriers to access, yet the presence of strong social networks overcame those barriers in accessing care.[79]

Nepal and neonatal health

Nepal is a landlocked country bordering India and Tibet, with a population of approximately 30 million people (July 2013 estimate).[86] The country is comprised of 102 castes and ethnic groups, and while Hinduism is the dominant religion, many practice Tibetan Buddhism and Islam as well.[87] Nepal is divided roughly into three ecologic regions, running east to west: the Himalayan mountain range in the north, a hilly region in the center, and the *terai* (the plains) region in the south. The *terai* region geographically and ethnically resembles other areas of South Asia, like northern India, Bangladesh, and Pakistan, and is the most densely populated region in Nepal.

Nepal has successfully met both its Millennium Development Goal #4 (reduce by two-thirds the under-five mortality rate between 1990 and 2015, a target of 45 deaths per 1000 live births for Nepal) and #5 (reduce by three quarters the maternal mortality ratio between 1990 and 2015, a target of 193 deaths per 100,000 pregnancies for Nepal).[88] The most recent Demographic and Health Survey conducted in 2011 reported a neonatal mortality rate of 33 per 1000 live births.[89] In the 15 years leading up to that survey, under-five mortality dropped by 54% (from 118 to 54 deaths per 1000 live births), while neonatal mortality decreased by a lower rate of 34%. Health care utilization has increased significantly over the same span, with 50% of mothers receiving four or more antenatal care visits (compared to 14% in 2001) and 35% delivering their infants at a facility

(compared to 9% in 2001). Indicators for immediate newborn care, such as drying, wrapping, delayed bathing, and proper cord care improved as well.[89]

Nepal has very actively included neonatal health in national strategies; the Ministry of Health and Population put forth a National Neonatal Health Strategy in 2004, and subsequently, a Nepal Safe Motherhood and Neonatal Long Term Plan 2006–2017 was also published, bringing newborns to the forefront. The Nepal Safer Motherhood Program (2005-2010) committed to longer term health systems strengthening,[90] and included the ongoing Safe Delivery Incentive Programme that offers cash to women who attend antenatal care visits and deliver at a facility.[78] The Ministry of Health and Population also began the Community-Based Newborn Care Program, which strives to deliver evidence-based interventions to communities around the country. The package of interventions focus on promoting facility deliveries and clean home delivery practices, postnatal care, community case management of pneumonia and possible severe bacterial infection, care of low birthweight newborns, prevention and management of hypothermia, and recognition and management of birth asphyxia. As of June 2015, the program was operating in 42 out of 75 districts (personal communication). Innovative research conducted in Nepal on neonatal interventions have been both pushing and complimenting these national policies. The Morang Innovative Neonatal Intervention (MINI) Project showed that Female Community Health Volunteers can provide initial treatment to neonates for suspected pneumonia prior to referring them to a facility.[91] The Mother Infant Research Activities (MIRA) group, active in Makwampur and Dhanusha Districts, was the first to report on the positive effects of peer mothers' groups on pregnancy and

neonatal outcomes.[92] The Nepal Nutrition Intervention Project – Sarlahi (NNIPS), the organization under which this dissertation project was conducted, showed that application of chlorhexidine to the umbilical cord immediately after birth reduces neonatal mortality by a quarter.[93]

Despite the aforementioned improvements and commitment to neonatal health, the national neonatal mortality rate has stagnated. The 2006 and 2011 DHS both report a neonatal mortality rate of 33 deaths per 1000 live births. Furthermore, the percentage of neonatal deaths occurring in the early neonatal period has increased from 70 to 85%, suggesting a drop in mortality attributable to causes such as infections but minimal change in causes operating most proximate to the time of birth, such as preterm birth and intrapartum-related complications.[94] Also, across the three Nepal DHS that have been conducted (years 2001, 2006, 2011), the differential in neonatal mortality by wealth quintile has continued to increase,[94] suggesting inequitable health improvement.

Summary

Both globally and in Nepal, rates of neonatal mortality have declined significantly since the introduction of the Millennium Development Goals. However stillbirths and neonatal deaths attributable to intrapartum-related complications remain high. Intrapartum-related complications have traditionally been viewed as unpredictable, yet there are several low-prevalence obstetric risk factors that could potentially help identify in the antenatal period women who have high risk of pregnancy complications. Non-cephalic presentation, multiple gestation, and placenta previa all are considered risk

factors for intrapartum-related complications, and require skilled birth attendance, ideally in a facility with C-section capacity. There are numerous barriers for women in low-resource settings to deliver at a facility. Such barriers need to be addressed to ensure reductions in adverse pregnancy outcomes resulting from intrapartum-related complications.

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Chapter 2: Research Context

Objectives

This dissertation research has three main objectives: 1) to estimate incidence of basic obstetric risk factors diagnosable by ultrasound and their risk of intrapartum-related complications in rural Nepal, 2) to determine the validity with which lower-level health workers are able to diagnose obstetric risk factors (non-cephalic position, multiple gestation, and placenta previa) using ultrasonography in rural Nepal, 3) to understand care-seeking behavior and perceptions associated with non-cephalic presentation in rural Nepal.

Specific aims

The following specific aims seek to highlight the disease burden and the potential to improve pregnancy outcomes specifically related to intrapartum-related complications in rural Nepal:

1) Burden of intrapartum-related complications associated with non-cephalic and multiple birth in rural Sarlahi District, Nepal

   a. To estimate the incidence of non-cephalic and multiple births respectively

   b. To determine if non-cephalic and multiple births respectively increases the risk of fresh stillbirths, early neonatal mortality, and neonatal encephalopathy

   c. Using incidence and risk data, to estimate the percent risk of fresh stillbirths, early neonatal mortality, and neonatal encephalopathy associated with non-cephalic and multiple births respectively

2) Community-based diagnosis by lower-level health workers of non-cephalic position, multiple gestation, and placenta previa using ultrasonography in rural Sarlahi District, Nepal

a. To determine the current level of awareness and utilization of obstetric ultrasonography in this community

b. To determine what proportion of women who experienced a non-cephalic or multiple birth were aware of their condition prior to delivery

c. To determine if lower-level health workers during home visits can accurately identify non-cephalic position, multiple gestation, and placenta previa using a portable ultrasound machine in the third trimester

3) Community perception of non-cephalic presentation in rural Sarlahi District, Nepal

a. To assess community perceptions of etiologies and consequences of non-cephalic presentation

b. To understand care-seeking behaviors associated with non-cephalic presentation

Summary of studies

Study 1 (Chapter 3). Association between non-cephalic / multiple birth and intrapartum-related adverse outcomes. This was a community-based prospective cohort study examining the incidence of select obstetric risk factors diagnosable by ultrasound in rural Nepal, and their associations with adverse pregnancy outcomes. Data on non-cephalic presentation (associated with obstructed labor, also more likely among preterm

births) and multiple births (associated with obstructed labor / retained second twin, higher rates of preterm birth and fetal growth restriction) were collected. These data were collected during a home visit immediately after delivery of the child, from maternal recall. The outcomes of interest are fresh stillbirth, early neonatal mortality, and neonatal encephalopathy. All stillbirths were categorized as macerated or fresh to discern the timing of the stillbirths; a majority of fresh stillbirths is expected to be due to intrapartum causes. We used the following signs to identify neonatal encephalopathy: seizures or two of the following three neurologic symptoms (lethargy, poor suck, or respiratory depression, defined as <40 breaths per minute based on examination by a study worker).[1] Data collectors made home visits immediately after birth, at day 3, and at day 7, allowing us to obtain an accurate estimate of day/hour of birth and death.

Study 2 (Chapter 4). Awareness and utilization of obstetric ultrasonography. Among the women enrolled in Study 1, we conducted a cross-sectional survey regarding the awareness of obstetric ultrasonography and utilization during their most recent pregnancy. The data were collected at a home visit immediately following delivery. We conducted regression analyses to identify reproductive health-related, socioeconomic, and other maternal characteristics that increased the likelihood of a woman receiving an obstetric ultrasound exam.

Study 3 (Chapter 5). Validity of home-based sonographic diagnosis of obstetric risk factors by lower-level health workers. This was a community-based validation study, examining the validity with which auxiliary nurse midwifes (ANM, high school graduates with 18 months of basic midwifery training) with limited training can use a

portable ultrasound machine to detect three major risk factors of adverse intrapartum-related outcomes in the mid/late third trimester: non-cephalic position, multiple gestation, and poor placental position (placenta previa). The analysis consisted of calculating sensitivity, specificity, positive predictive value, negative predictive value between each ANM and the gold standard diagnosis, a reading of the images conducted by certified sonographers. We also calculated the kappa statistic of the diagnoses for each pair of assessors (three ANMs involved total) to estimate inter-rater reliability.

Study 4 (Chapter 6). Care-seeking / care-giving behavior and perceptions of etiologies and consequences associated with non-cephalic presentation. Non-cephalic presentation is expected to be highly predictive of intrapartum-related complications and adverse outcomes. There is limited literature on how non-cephalic presentation is perceived by the community in relation to pregnancy outcomes, and whether and how families choose to seek care when a fetus presents in poor position. We conducted in-depth interviews with mothers who recently experienced a non-cephalic birth and/or the female decision-makers in their household to discuss their diagnostic and care-seeking behavior and perceptions pertaining to etiologies and consequences of non-cephalic presentation. We also conducted focus groups with mothers and grandmothers in the community to understand community perceptions and norms pertaining to non-cephalic presentation.

Study 4b (Chapter 7). Barriers and facilitators to intrapartum care-seeking. As a part of the data collection in Study 4, we summarized data on barriers that keep pregnant

women in rural Nepal from seeking and/or receiving intrapartum care at a birthing facility, and also to explore what motivated those who did deliver at a facility.

Study Population

The thesis research was conducted at the Nepal Nutrition Intervention Project – Sarlahi (NNIPS) study site, a project organization of the Johns Hopkins Bloomberg School of Public Health in partnership with the Nepali NGO Nepal Netra Jyoti Sangh. The site is located in rural Sarlahi District, situated in the southern low-lying *terai* region. The district has a population of roughly 600,000 people. The study area covers 34 Village District Committees (VDC, an administrative unit) out of 103 VDCs in Sarlahi District and encompasses roughly 300,000 people. The residents are mostly subsistence farmers, and are mainly comprised of two major ethnic groups: Madheshi (associated with the southern plains / northern Indian area) and Pahadi (associated with the hill area).[2] Madheshis generally belong to a lower socioeconomic stratum in comparison to Pahadis.[2]

The NNIPS study site has been operating since 1988, with a focus on researching maternal, newborn, and child health interventions. The first study was a randomized control trial on the impact of Vitamin A supplementation on child mortality.[3] Other studies include the impact of maternal Vitamin A supplementation on pregnancy outcomes,[4] the impact of maternal multiple-micronutrient supplementation on pregnancy outcomes,[5] and the impact of application of chlorhexidine (antibiotic) ointment on the umbilical cord on neonatal mortality.[6] The two most recently completed studies were a study on the impact of maternal influenza vaccination on the incidence of influenza-like

illness among mothers and newborns and a study on the impact of installing reduced-emission cookstoves on the incidence of acute respiratory infections among children and on pregnancy outcomes.

Parent trial for this study

The thesis research was nested in the Nepal Oil Massage Study, a cluster randomized community-based trial examining the impact of topical application of sunflower seed oil neonatal mortality and morbidity, compared to traditionally-used mustard seed oil (Clinicaltrials.gov NCT01177111). In rural South Asia, families rigorously massage their newborns using mustard seed oil, under the perception that the massages promote strength, health, and warmth.[7] However, the investigators hypothesize that the combination of the abrasive components of mustard oil and the weak skin barrier of newborns (particularly those born preterm) may contribute to morbidity (e.g. skin infection) and/or mortality.[7] More specifically, the primary aims are: 1) to determine if full-body sunflower seed oil massage of neonates in Sarlahi District, Nepal during the neonatal period can reduce neonatal mortality risk by at least 20% compared to neonates receiving the current standard practice of mustard oil massage, 2) to determine if full-body sunflower seed oil massage of newborns in Sarlahi District, Nepal during the neonatal period can reduce the incidence of probable severe disease by at least 25% compared to newborns receiving the current standard practice of mustard oil massage. The parent trial began enrollment in November 2010 and is ongoing (as of December

2015), but all data reported in this thesis covers the time period between March 2014 and September 2015.

Methods. Married women of reproductive age (15-40 years of age) were surveilled for new pregnancies every five weeks by female data collectors; a pregnancy test (Easytest rapid test card) was provided if women reported having had no menstrual period since the prior visit. Positive tests led to recruitment and consent to study participation, followed by collection of the woman's reproductive and pregnancy history, tobacco and alcohol use, anthropometric measurements, and socioeconomic information. The enrolled women received monthly visits to collect additional data on illness during pregnancy. In late pregnancy (around 32 weeks gestation, based on date of last menstrual period), enrolled women received a visit at which massage oil was provided and were encouraged to use the oil for massage after the baby's birth. Enrolled women and their families were instructed to immediately notify the study staff upon birth of the child.

Data on labor and delivery conditions (e.g. location of delivery, attendants at delivery, complications), immediate newborn care, and newborn health status (e.g. stillbirth or live birth, birthweight, morbidities) were collected during a visit immediately after the staff received birth notification. This visit occurred within 72 hours of birth for 81.9% of the enrolled women. The mothers received a daily visit from study staff for the first week following childbirth to encourage use of the oil provided by the study rather than their own oil. The mothers received a visit from a separate staff member on days 1, 3, 7, 10, 14, 21, and 28 to collect information on oil usage and neonatal and maternal

mortality and morbidities. For neonatal and maternal deaths, a verbal autopsy was conducted.

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Chapter 3: Association between non-cephalic / multiple birth and intrapartum-related adverse outcomes

Background

Intrapartum-related complications are the second leading cause of neonatal death and the third leading cause of under-five death worldwide. Estimates for the year 2013 reported 662,000 (95% CI: 421,000-1,054,000) neonatal deaths attributable to intrapartum-related complications (11% of under-five deaths) and a third of the world's stillbirths.[1] Combined, intrapartum-related complications account for the loss of 74.6 million disability adjusted life years according to 2012 estimates.[2] Early identification of risk and access to a skilled birth attendant who can promptly recognize obstetric complications are likely to be the most effective in reducing intrapartum-related mortality.[3] An estimated 60 million women still deliver at home globally, of whom over 85% have no skilled birth attendant at delivery.[3] Limited access to care makes antepartum risk factor detection all the more important.

As access to obstetric sonography in low-resource settings increases, quantifying the incidence and burden of risk factors identifiable via ultrasound can guide appropriate strategies for incorporating and promoting diagnostic technologies into the health system. Non-cephalic presentation and multiple gestation (e.g. twins) are two such ultrasound-identifiable factors that may be highly predictive of intrapartum-related complications.

We utilized data from the parent study to examine non-cephalic presentation and multiple gestation as potential risk factors for intrapartum-related adverse pregnancy outcomes. A high burden of mortality and morbidity attributable to these conditions

could justify the expense of screening programs or systematic antenatal referral for obstetric ultrasonography to better prepare mothers and their families for complications.

Preliminary analysis on data from previous study

Prior to beginning this study, we conducted exploratory analysis on existing data from a study conducted at the same study site between 1998-2001 (NNIPS-3).[4] These data were then used for sample size calculations for the present study. Between December 1998 and April 2001, 4926 pregnant women were enrolled in a double-blind cluster-randomized community trial, exploring the effects of maternal micronutrient supplementation on birthweight. Details are available in another publication.[5] The study area encompassed 30 village development committees, which contained 426 sectors. Each sector contained 75 to 150 households. Each of these sectors was then randomized to a supplementation arm in blocks of five. The clusters were randomized to one of five micronutrient supplementation arms: folic acid (400 μg), folic acid and iron (60mg), folic acid, iron and zinc (30mg), multiple micronutrients (folic acid, iron, zinc, vitamin D 10μg, vitamin E 10mg, thiamine 1.6mg, riboflavin 1.8mg, vitamin B-6 2.2mg, vitamin B-12 2.6μg, vitamin C 100mg, vitamin K 64 μg, niacin 20mg, Cu 2mg, Mg 100mg), and a control group. Each group, including the control group, also received vitamin A (1000 μg retinol equivalents).

Our field workers made home visits every five weeks to married women of reproductive age (15-45 years old). Those who reported not having a menstrual period since the worker's previous visit were provided a pregnancy test (Clue, Orchid

Biomedical Systems). If the pregnancy was confirmed, she was enrolled into the trial. At the time of enrollment, data such as maternal morbidity, alcohol and tobacco use, anthropometry (weight, height, mid-upper arm circumference), nutritional intake, and socioeconomic and demographic characteristics were collected. At a follow-up visit in the third trimester, time-varying variables among the aforementioned list were collected again. Then, the mothers were tracked for birth outcomes, and their infants followed until they turned one year of age.[6] Log-binomial regression was run to estimate the risk ratio of adverse pregnancy outcomes among non-cephalic and multiple births respectively. The models were adjusted for potential confounders: preterm birth, facility delivery, primiparity, and literacy for non-cephalic birth, and preterm birth, facility delivery, maternal height <145cm, and literacy for multiple birth. Stata version 13.0 was used for the analysis.

Table 3.1 summarizes the basic maternal and neonatal health indicators from the study. Of the 4016 live births with data, the non-cephalic presentation rate was 3%, and of the 4160 mothers, 1% had a multiple birth. Both non-cephalic presentation and multiple birth had significantly heighted risk of intrapartum-related mortality and morbidity outcomes. When combining stillbirths and early neonatal mortality into a single outcome, non-cephalic birth had a four-fold increase (aRR 3.92, 95% CI: 1.91-8.06) compared to cephalic birth, and multiple birth had an eight-fold increased risk (aRR 7.56, 95% CI: 4.59-12.43) compared to singletons (Table 3.2). It should be noted, however, that the data from this study did not allow for differentiation of fresh stillbirths from macerated stillbirths; the macerated stillbirths are unlikely to be caused by

intrapartum-related complications.

Methods

The main exposures of interest were non-cephalic presentation and multiple birth. We categorized maternal report of fetal presentation as cephalic (head presenting first), non-cephalic (feet, umbilical cord, arm, or buttocks presenting first), or Cesarean section (C-section). Those who underwent C-section or had a multiple birth were excluded from the main analysis on fetal presentation, but a sensitivity analysis was conducted with multiple births included in the analysis. Any pregnancy with more than one fetus was categorized as multiple birth. We examined outcomes that are most proximate to the time of labor and delivery: fresh stillbirth, defined as a stillbirth with maternal self-report of the fetal skin not being pulpy (stillbirth assumed to have occurred within 12 hours prior to delivery if the skin is not pulpy), first day neonatal mortality (within the first 24 hours of life), and early neonatal mortality (within the first seven days of life). We also examined neonatal encephalopathy (NE) as an adverse outcome using a previously defined clinical signs-based definition: report of convulsions/seizure or two of the following: lethargy, poor suck, or respiratory rate <40 breaths per minute.[7] Only those who had morbidity data available at some point within the first seven days were categorized for NE, including those who later experienced early neonatal death. We also created an aggregate "any adverse outcome" variable of having any of the aforementioned outcomes. In addition, we asked those women who had a non-cephalic or multiple birth whether they were aware of the condition prior to delivery, how they found

out, and whether any birth preparations specific to the condition were made in light of their knowledge. All data except fetal presentation at birth were already being collected as a part of the parent study. Data on fetal presentation was collected starting March 2014.

Analysis

We collected data from 6678 women over a one-year period (March 2014 to March 2015). Using the 3% incidence of non-cephalic birth from the preliminary analysis, along with a Type I error of 0.05 (two-sided test), a power of 0.90, 3% loss to follow-up, and assuming 5% perinatal mortality rate among cephalic births, we had the power to detect a risk ratio of 2.19 of perinatal mortality, comparing non-cephalic to cephalic births.

We calculated unadjusted and adjusted risk ratios (RR) using log-binomial regression.[8] We ran several models to examine the impact of external factors on the association between non-cephalic presentation and/or multiple birth with adverse outcomes. We examined how the association would change with the inclusion of the following potential confounders in separate regression models: 1) preterm, defined as gestational age less than 37 completed weeks (is associated with non-cephalic presentation, as fetuses are more likely to be in non-cephalic position earlier in gestation, and associated with multiple birth), 2) clinical care-related variables (facility vs. home birth, use of uterotonics during labor), 3) maternal and fetal size (maternal height <145cm, neonatal birthweight <2500g, limited to weights taken within the first 72 hours

of birth), 4) reproductive health-related variables (maternal age and parity at pregnancy), and 5) socioeconomic and demographic variables (maternal literacy, ethnicity, land ownership). Birthweight is not measured for stillbirths, thus excluded as a covariate for the models for the stillbirth and aggregate "any adverse outcome" outcomes.

Gestational age was calculated using the date of last menstrual period, based on maternal recall at enrollment. Given the five-weekly pregnancy surveillance system, the recall was generally shorter than five weeks. Covariates that were significant at the $p<0.10$ level in each of the aforementioned models using the aggregate "any adverse outcome" as the dependent variable were included in the final multivariate models. Using the estimated RRs and prevalence data, we also calculated the percent risk of the outcomes that is associated with non-cephalic presentation and multiple birth respectively. We used Stata version 13.0 (Stata Corp.) for analysis.

In addition, we conducted semi-structured interviews at all birthing facilities in our study area (n=12) to understand their protocol for handling non-cephalic or multiple birth. The interviews were conducted in March 2014 with the highest-level provider available at the facility at the time of visit.

We obtained ethical approval from the Institutional Review Boards of Johns Hopkins Bloomberg School of Public Health in the U.S. and the Tribhuvan University Institute of Medicine in Nepal respectively.

Results

Data for 6894 births were collected, excluding those who experienced an abortion or a miscarriage (fetal demise at <28 weeks gestation), between March 25, 2014 and March 24, 2015. Of these, 161 births were excluded as their mothers were enrolled in a substudy that provided home-based ultrasound exams (Chapter 5), leaving 6623 singletons and 110 twins (55 pairs), for a total of 6678 mothers included in the study. The characteristics of the mothers are available on Table 3.3.

For singletons, 6387 births had a valid response regarding fetal presentation when excluding women who underwent a C-section (n=202) and those reporting unknown fetal presentation (n=34). 2.1% reported a singleton fetus being in non-cephalic presentation at the time of birth. Compared to term (≥37 weeks) babies, the rate of non-cephalic presentation was statistically significantly higher among preterm (<37 weeks) births (3.1% vs. 1.8%, $p<0.001$) and even higher among very preterm (<34 weeks) births (6.4% vs. 1.8%, $p<0.001$).

Rates of fresh stillbirth, early neonatal mortality, and NE were all statistically significantly higher among fetuses in non-cephalic presentation (Table 3.4). Among singleton non-cephalic infants, there was a fresh stillbirth rate of 168/1000 births (21 of 125 births) compared to 13/1000 births (80 of 6229 births) among cephalic infants, an early neonatal mortality rate of 67/1000 live births (7 of 104 births) compared to 13/1000 live births (80 of 6149 births), and an NE rate of 20.9% (18 of 86 infants) compared to 4.7% (261 of 5609 infants). Combined, of the 111 non-cephalic singleton births with data on stillbirth and mortality and morbidities up to seven days of life, 44 (39.6%)

experienced an adverse outcome; among cephalic singleton births, 402 of 5720 (7.0%) experienced an adverse outcome.

The twinning rate was 8.2 out of 1000 pregnancies (55 twin pairs out of 6678 pregnancies). No triplets were reported in the study. Two C-section deliveries of twins were excluded from the analysis. While fresh stillbirth rates were not statistically significantly different between singletons and twins, all other outcomes were statistically significantly higher among twins (Table 3.4). Among the 55 pairs of twins described in our analysis, 13 of them (23.6%) had a retained second twin (the second twin delivered beyond 30 minutes after the first twin). The non-cephalic presentation rate was 13.5% for first twins and 20.0% for second twins, and twins who were non-cephalic had an adverse outcome rate of 41.7% compared to twins who were cephalic who had a rate of 22.6%.

Fetal presentation among singletons

We selected the covariates to include in the final model for non-cephalic birth after examining statistically significant covariates (at the $p<0.10$ level), using the aggregate "any adverse outcome" as the outcome of interest. Preterm birth, the location of delivery (facility vs. home), and primiparity were all significantly associated with adverse outcomes, and were included in the final model (Table 3.5). We also included the woman's literacy to control for potential residual confounding associated with socioeconomic status.

The final model estimated a five-fold increased risk of adverse outcomes, for non-cephalic compared to cephalic presentation (aRR 4.87, 95% CI: 3.74-6.34). When

including multiple births and their individual presentation at birth into the analysis, the association did not change significantly (aRR 4.76, 95% CI: 3.71-6.10). Non-cephalic presentation had the strongest association with fresh stillbirth, with a 13-fold increase in risk (aRR 12.69, 95% CI: 7.96-20.21).

20.5% of fresh stillbirths, 1.1% of early neonatal mortality, and 4.6% of NE were attributable to non-cephalic presentation, or 7.8% of all of these outcomes combined.

Multiple births

Preterm birth, the location of delivery (facility vs. home), primiparity, and maternal stature under 145cm were all significantly associated with adverse outcomes, and were included in the final model (Table 3.6). We also included woman's literacy to control for potential confounding associated with socioeconomic status. The final model showed a three-fold increased risk of adverse outcomes, for multiple birth compared to singletons (aRR 2.97, 95% CI: 2.06-4.28). Multiple birth was not statistically significantly associated with fresh stillbirth. However, there was a six-fold increase in risk of early neonatal mortality (aRR 5.91, 95% CI: 3.54-9.85). In a bivariate analysis, retained second twins had a three times higher risk of adverse outcomes than second twins who were not retained (RR 3.62, 95% CI: 1.58-8.25). Multivariate analysis was not conducted due to the small sample size of twins (n=55 pairs).

4.7% of early neonatal mortality, 1.2% of NE, and 1.9% of all adverse outcomes combined were attributable to multiple birth.

Awareness of condition prior to start of labor

Among the mothers who experienced a singleton non-cephalic delivery (n=131), only 34 (25.4%) of them were aware prior to the start of labor. Of the 34, a majority (67.6%) knew through an ultrasound exam, 17.6% through self-exam, and the remaining through physical examination by a traditional birth attendant, an auxiliary nurse midwife, a nurse, or a doctor (multiple responses were allowed). Among the 34 individuals who knew, eight individuals (23.5%) did not make any particular birth preparation, eight individuals (23.5%) consulted a facility or a doctor, 16 (47.1%) planned a facility delivery, five (14.7%) made financial arrangements, and three (8.8%) had a certified clinical personnel attempt to turn the fetus around. When including the mothers who were not aware of fetal presentation prior to the start of labor, only 19.8% of the 131 mothers made birth preparations for non-cephalic delivery. (Table 3.7) The rate of adverse outcomes (only among infants who had data on stillbirth, early neonatal mortality, and neonatal encephalopathy in the first week of life) was lower among those who knew the presentation prior to delivery compared to those who did not (6 of 28 who knew, 21.4% vs. 38 of 83 who did not know, 45.8%, p=0.023). The adjusted risk ratio of non-cephalic presentation for adverse outcomes was 2.74 (95% CI: 1.40-5.36) among women who knew of non-cephalic presentation prior to delivery and 4.99 (95% CI: 3.91-6.38) among those who did not, both compared to cephalic presentation.

Among the mothers who had a multiple birth (n=55), only 20 (36.4%) of them were aware before labor started. Of the 20, 16 (80.0%) knew through an ultrasound exam. Among the 20 individuals who knew, 7 (35.0%) did not make any birth preparation.

When including the mothers who were not aware of the multiple gestation prior to the start of labor, only 23.6% of the 55 mothers did anything to prepare for multiple birth. (Table 3.8)

Care provided at birthing centers located in the study area

Twelve birthing centers (four primary health care centers, five health posts, one sub-health-post, one private facility, and one NGO-run facility) were identified in our study area. The district did not have a facility with C-section capacity as of September 2015, and the nearest facilities with that capacity were located a three-to-four hour drive away in Birganj to the west and Janakpur to the east.

The policy of handling breech deliveries differed by each birthing center. Six facilities attempt the delivery and four facilities indicated that they refer immediately to a higher-level facility unless the mother is dilated beyond a certain point (three said "if fully dilated" and one said "5cm or more"). One said that their policy is to refer, but patients rarely comply. One auxiliary nurse midwife said that her facility has to refer, as there are no skilled birth attendants (SBA) available at the facility. She added that she would "get in trouble" if she tried a breech delivery, as she is not an SBA. One other facility stated that it did not have a SBA, and two other facilities reported that an SBA was assigned to the facility, but was not present at the time of interview. While most facilities indicated that they would immediately refer for more complicated non-cephalic presentation (transverse position, cord prolapse, etc.), one provider at a health post indicated, "If the cord comes out first, we just move it aside."

There was also no consistent policy for multiple births. Four birthing centers claimed they refer unless the mother was fully dilated. The remaining indicated that they conduct the deliveries and only refer if there is a problem.

Discussion

Globally and in Nepal, intrapartum-related complications account for a large percentage of stillbirths and neonatal mortality. Furthermore, the morbidity burden is often ignored; in 2010, intrapartum-related hypoxic events resulted in 1.15 million cases of NE, of whom 287,000 died and 413,000 experienced impairment. Impairment rates are expected to increase as survivors increase.[9] Our study showed significantly higher risk of intrapartum-related mortality and morbidity among fetuses born in non-cephalic presentation or were twins. We estimated that a little under 10% of adverse intrapartum-related outcomes (fresh stillbirth, early neonatal mortality, NE) is attributable to either non-cephalic and/or multiple birth.

Non-cephalic presentation operates on intrapartum-complications through restriction of fetal oxygen (hypoxia) due to prolonged labor and fetal entrapment.[10] Even if the fetus survives such insult, the failure to receive oxygen for an extended period of time could influence the brain, causing mild to severe impairment. For multiple births, retention of the second twin is common, leading to complications.[11-13] We only address mortality and NE in our paper, but both non-cephalic presentation and multiple gestation may also increase the risk of other adverse health outcomes. There is most likely underreporting of morbidities including fractures and spinal cord injury for the

fetus/neonate and genital tract lacerations for the mother.[14] A Nigerian study reported a maternal mortality ratio of 895 maternal deaths per 100,000 live births associated with twinning.[15] While we only crudely categorized the deliveries in our study as non-cephalic versus cephalic and singleton versus multiple, there are more subtleties to fetal presentation that make some deliveries more dangerous than others. For instance, approximately 5% of term breech fetuses are in a position where the fetal head is hyperextended.[14] Delivering those fetuses vaginally could injure the spinal cord.[14] Multiple births with malpresentation (breech or transverse) can also further endanger them. Previous publications have reported a large proportion of twins having at least one twin presenting in non-cephalic position.[12,13,16] We did not explore the association between multiple birth and adverse outcomes, stratified by fetal presentation, due to the small sample size. At the University of Nigeria Teaching Hospital, approximately a sixth of the twins delivering at the hospital between 1991 and 2000 had a retained second twin, and the second twin experienced a perinatal mortality rate of 288.5 per 1000 deliveries (1.7 times higher than the first twin). Malpresentation was the largest contributor (54%) to the retention.[12] Another Nigerian study reported roughly 40% of all twin births having at least one twin presenting in non-cephalic position.[16]

Many of these deaths and morbidities are preventable with skilled attendance at labor and use of basic equipment. However, some complications require access to comprehensive emergency obstetric care facilities that can provide C-section if needed. C-section rates are as low as 5% in rural South Asia and near 0% in rural Sub-Saharan Africa,[17] although the expected rate should be about 15% based on the expected

prevalence of obstetric complications requiring c-section.[18] A review estimated that for each one percent increase in C-section rates in a country (up to 8%), stillbirth rates drop by approximately 1.6 stillbirths per 1000 births.[19] Another analysis using WHO data also reported proportional reductions in stillbirths with increases in C-section rates, up to the C-section rate of 10%.[20] Our study population reported a C-section rate of 2.9%.

We have categorized outcomes that are closest to the time of birth as intrapartum-related mortality and morbidity. We also controlled for various confounders available in our data. However, these deaths may have occurred for other reasons, both controlled and not controlled for in our regression models, as we do not have clinical assessments of cause of death. For instance, there are higher preterm rates among both non-cephalic and multiple gestation infants. While we statistically controlled for preterm birth, we may see some residual confounding. Also, multiple birth, placenta previa, and hydrocephaly are some risk factors associated with non-cephalic birth. Even with potential misattribution of causation to non-cephalic presentation or to multiple births, those infants would benefit from the referral, allowing for these infants with particularly heightened risk of mortality and morbidities to have access to the highest quality care available.

Detection and management of breech using C-section was one of the 16 interventions identified in 2005 Lancet Neonatal Series as an intervention to reduce neonatal mortality rates.[21] Ultrasonography is the gold standard diagnostic method for both non-cephalic position and multiple gestation. While other non-ultrasound-based methods have been used, existing evidence shows variable validity. An abdominal palpation method called the Leopold's maneuver has been used to identify fetal position.

However, published studies have reported a range of validity of the diagnosis. One study reported a very low sensitivity of 28%, a specificity of 94%, and a low kappa value of 0.13 against ultrasound diagnosis.[22] Another study reported a sensitivity of 53% versus ultrasound diagnosis. In that study, there was no dose-response relationship in validity with years of clinical experience.[23] A third study found a sensitivity of 88% and a specificity of 94%, using midwives with 10-16 years of experience.[24] Another study had sensitivity values ranging from 31 to 82% depending on the assessor.[25] However, all of these studies had major methodological issues, such as small sample size, failure to blind the assessors from maternal request for an ultrasound exam, the maneuver being conducted in the second trimester, and/or validation by very few assessors. All of the above studies were conducted in the U.S. The most recently published validation study conducted in Australia in 2003-2004 used midwives, residents, registrars, and obstetricians for the screening, was appropriately powered (1633 women screened), and found a sensitivity and a specificity of 70% and 95% respectively.[26] The variable validity and difficulty in standardizing the skill among even the highest trained health workers make access to ultrasonography all the more important.

With the proliferation of ultrasonography, however, there needs to be regulation and community sensitization in low-resource settings. Aside from government-run facilities, unregulated ultrasound clinics are beginning to flourish in South Asia, most for the purpose of fetal sex determination. In India, prenatal sex selection has been illegal since 1996, yet there is minimal enforcement, as most of the activity occurs in unregulated private clinics.[27] Companies like General Electric that are active players in

the international ultrasound market have also reflected on how best to promote ultrasound technologies in areas where they may be used for such purposes.[28] In addition, it is unclear to what extent community members are aware of the benefits of obstetric ultrasonography and have access; 64.1% had heard of ultrasound and 26.8% of women enrolled in our parent study had an obstetric sonographic exam during their most recent pregnancy (Chapter 4). It is important that the use of ultrasound for sex selection not deter the health system from incorporating ultrasound technologies into their practices, as the technology would allow for early detection of obstetric risk factors, and potentially allow for better birth preparation by households.

We observed increased risk of adverse intrapartum events with preterm birth and facility delivery in the non-cephalic presentation regression model, and with facility delivery and short maternal stature in the multiple gestation regression model. The association between preterm birth and adverse birth outcomes are well-documented, and the association between short maternal stature and adverse birth outcomes may be operating through low uterine volume contributing to fetal growth restriction, early spontaneous labor via earlier filling of the pelvis[29,30] or through consequences of chronic maternal malnutrition.[31] We believe that the association between facility delivery and adverse outcomes may be due to the severity of the health condition and/or the late timing of arriving at the facility. Families may seek facility-level care only when family members sense that the condition is severe or after they experience a complication at home; thus we expect a disproportionate number of complicated cases to be seeking care at the facility.

In the late 1980s, there was a push within the maternal health community to explore the concept of prenatal risk screening to reduce intrapartum-related deaths.[32] Many of the risk factors that were examined were high in prevalence (i.e. first births, maternal short stature), which meant that while the screening successfully captured a large proportion of mothers who later experienced adverse outcomes (high sensitivity), it also captured many who did not require special care (low positive predictive value).[33] This essentially ended the pursuit of this agenda at the time. Our findings, along with increasing access to ultrasonography, may contribute to the revival of the agenda of antenatal risk screening.

There are limitations to the data. The question regarding fetal presentation was based on maternal recall, and it is unclear how often a mother would have been notified of the presentation of the fetus. However, family members were often present at both the time of delivery and during the data collection interview. There is also a study from Mozambique that reported on maternal recall of fetal presentation, and observed high validity.[34] Thus, we expect minimal misclassification. We however expect some misclassification of the adverse outcomes, in that some of those outcomes may not have occurred due to intrapartum-related insult. We also did not collect data on the reason a woman underwent C-section. Several of the women in our study reporting Caesarean delivery may have undergone that procedure because the fetus was non-cephalic or because the pregnancy was multiple gestation. By excluding those potential cases, we may be incorrectly estimating the risk of non-cephalic birth or multiple birth. For the outcome of neonatal encephalopathy, not all children surviving seven days and beyond

had a morbidity assessment conducted within seven days to see whether the child had clinical signs of neonatal encephalopathy.

Conclusion

Non-cephalic and multiple births experience significantly increased risk of adverse intrapartum-related pregnancy outcomes. Despite the low incidence, the percent of adverse pregnancy outcomes attributable to these two factors are not negligible. These findings may justify investments in screening programs to identify these women prior to the time of delivery and encourage appropriate birth preparation. Future research is needed to explore how early diagnosis may impact health outcomes.

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Tables

Table 3.1: Neonatal, fetal, and obstetric-related indicators from the NNIPS-3 study (1998-2001)

Health indicators	**N**	**Rate / %**
Neonatal mortality rate	3953	41.9 deaths per 1000 live births
Early neonatal mortality rate	4127	30.8 deaths per 1000 live births
Stillbirth rate	4202	35.9 deaths per 1000 births
Low birthweight rate	3525	38.8%
Preterm rate	4116	22.4%
Small-for-gestational-age rate	3300	56.0%
Facility delivery rate	4009	6.0%
Cesarean section rate	4012	0.5%
Non-cephalic presentation rate	4016	2.9%
Multiple birth rate	4160	1.0%

Table 3.2: The association between non-cephalic / multiple birth and intrapartum-related outcomes from the NNIPS-3 study (1998-2001)

	Unadjusted risk ratio (95% CI)	**Adjusted risk ratio (95% CI)**
Non-cephalic birth as exposure*		
Stillbirth***	222.79 (88.96, 557.94)	23.56 (4.05, 137.1)
Day 1 mortality	7.93 (4.01, 15.66)	4.22 (1.56, 11.41)
Early neonatal mortality	5.02 (2.87, 8.80)	3.49 (1.60, 7.63)
Stillbirth or early neonatal mortality	13.43 (9.99, 18.05)	3.92 (1.91, 8.06)
Birth asphyxia****	1.63 (1.36, 1.95)	1.60 (1.30, 1.97)
Multiple birth as exposure**		
Stillbirth	2.81 (1.43, 5.53)	---
Day 1 mortality	8.56 (4.37, 16.78)	5.80 (2.89, 11.68)
Early neonatal mortality	7.39 (4.58, 11.92)	4.85 (3.00, 7.83)
Stillbirth or early neonatal mortality	4.42 (3.03, 6.45)	7.56 (4.59, 12.43)
Birth asphyxia****	1.65 (1.38, 1.98)	1.51 (1.21, 1.90)

*Controlled for preterm, facility delivery, primiparity, literacy
**Controlled for preterm, facility delivery, height <145cm, literacy
***Fresh and macerated not distinguished.
****Defined as failed to cry/unable to breath at birth or convulsions or unable to suckle[35]

Table 3.3: Characteristics of study participants (n=6678 mothers, 6705 infants)

Characteristic	%	Mean (SD)
Maternal age at delivery		23.3 (4.78)
<18 years old	8.4%	
18-<35 years old	88.9%	
≥35 years old	2.8%	
Maternal gravidity (excluding this pregnancy)		1.7 (1.7)
0	28.5%	
1-2	46.2%	
3-4	19.2%	
≥5	6.1%	
Facility delivery rate	45.4%	---
Location of delivery		---
At home	37.8%	
At her maternal home	14.6%	
At a health post/clinic	30.8%	
At a hospital	14.6%	
On the way to a facility	2.2%	
Outdoors	0.1%	
Maternal education		2.5 (4.1)
No years	68.2%	
1-9 years	20.3%	
≥10 years	11.5%	
Ethnicity		---
Madheshi	96.4%	
Pahadi	3.6%	
Maternal height		150.7 (5.6)
<145cm	14.2%	
145-150cm	29.4%	
150-155cm	34.5%	
≥155 cm	21.9%	
Birthweight (n=5515 with weight taken within 72 hours of birth)		2693 (420.7)
<2500g	30.8%	
Gestational age (n=6605 with feasible GA, between 24-46 wks)		39.2 (2.8)
<37 weeks	17.6%	
Small-for-gestational-age		---
Alexander reference (n=5482)	54.7%	
Intergrowth standard (n=4923)	43.2%	
Non-cephalic presentation (n=6469, excluding C-sections and unknowns)	2.2%	---
Multiple birth	16 per 1000 pregnancies	---

Table 3.4: Crude fetal and neonatal mortality and/or morbidity rates, by fetal presentation and singleton/multiple birth status

	Fetal presentation at delivery (among singletons)		**Multiple births**	
	Cephalic	**Non-cephalic**	**Singleton**	**Twins***
Fresh stillbirth	80/6229 (13 per 1000 births)	21/125 (168 per 1000 births)	105/6384 (16 per 1000 births)	3/104 (29 per 1000 births)
First day mortality	42/6149 (7 per 1000 live births)	5/104 (48 per 1000 live births)	53/6253 (8 per 1000 live births)	5/101 (50 per 1000 live births)
Early neonatal mortality	80/6149 (13 per 1000 live births)	7/104 (67 per 1000 live births)	87/6253 (14 per 1000 live births)	16/101 (158 per 1000 live births)
Showing symptoms of neonatal encephalopathy**	261/5609 (4.7% of live births)	18/86 (20.9% of live births)	280/5749 (4.9% of live births)	8/72 (11.1% of live births)
Any of the above outcomes***	402/5720 (7.0% of births)	44/111 (39.6% of births)	446/5831 (7.7% of births)	24/83 (28.9% of births)

The data exclude macerated stillbirths and C-sections

*There were no triplets in our study.

**Must have had at least one morbidity assessment pertaining to clinical signs of neonatal encephalopathy prior to day 7.

***Only includes births with data on stillbirth status and mortality/morbidity through day 7.

Table 3.5: Association between non-cephalic presentation and adverse intrapartum-related fetal/neonatal outcomes

	Fresh stillbirth RR (95% CI)	**First day neonatal mortality RR (95% CI)**	**Early neonatal mortality RR (95% CI)**	**Signs of neonatal encephalopathy (early neonatal period) RR (95% CI)**	**Any adverse outcome* RR (95% CI)**
Model 0					
Non-cephalic presentation	13.08 (8.37, 20.45)	7.04 (2.84, 17.43)	5.17 (2.45, 10.93)	4.50 (2.93, 6.90)	5.64 (4.40, 7.23)
Model 1 - preterm					
Non-cephalic presentation	12.93 (8.17, 20.47)	5.12 (1.89, 13.87)	4.17 (1.88, 9.24)	4.59 (3.00, 7.03)	5.46 (4.25, 7.03)
Preterm	1.93 (1.26, 2.96)	4.20 (2.36, 7.48)	3.53 (2.30, 5.40)	1.05 (0.77, 1.42)	1.48 (1.21, 1.81)
Model 2 - clinical care related					
Non-cephalic presentation	13.17 (8.41, 20.63)	6.99 (2.81, 17.34)	5.00 (2.37, 10.58)	4.07 (2.66, 6.22)	5.22 (4.07, 6.70)
Facility delivery (ref: home delivery)	0.95 (0.65, 1.40)	1.09 (0.61, 1.93)	1.28 (0.84, 1.95)	1.82 (1.44, 2.29)	1.45 (1.22, 1.74)
Received uterotonic during labor and delivery (ref: did not receive)	1.51 (0.39, 5.84)	3.24 (0.81, 13.05)	2.61 (0.85, 8.02)	0.52 (0.13, 2.05)	1.08 (0.54, 2.13)
Model 3 - maternal and fetal size					
Non-cephalic presentation	12.97 (8.30, 20.26)	N/A	1.53 (0.21, 11.05)	3.52 (2.04, 6.04)	5.60 (4.38, 7.15)
Maternal stature <145cm	1.36 (0.84, 2.20)	7.53 (0.47, 120.13)	3.81 (0.96, 15.17)	1.63 (1.10, 2.42)	1.50 (1.22, 1.85)
Newborn <2500g**	N/A	5.19 (0.47, 57.16)	6.32 (2.45, 16.27)	1.14 (0.85, 1.53)	N/A
Interaction term: maternal stature <145cm x newborn <2500g**	N/A	N/A	0.50 (0.10, 2.59)	0.85 (0.46, 1.58)	N/A
Model 4 - primiparity					
Non-cephalic presentation	12.84 (8.21, 20.10)	6.96 (2.81, 17.26)	5.07 (2.40, 10.72)	4.23 (2.76, 6.48)	5.37 (4.19, 6.88)
Primiparous	1.24 (0.83, 1.85)	1.14 (0.62, 2.10)	1.30 (0.84, 2.02)	1.49 (1.18, 1.89)	1.35 (1.12, 1.61)

Model 5 – Socioeconomic status					
Non-cephalic presentation	13.26 (8.48, 20.75)	6.70 (2.71, 16.57)	4.96 (2.35, 10.47)	4.49 (2.93, 6.88)	5.61 (4.38, 7.19)
Mother literate	1.18 (0.78, 1.80)	0.44 (0.20, 0.97)	0.56 (0.33, 0.95)	0.87 (0.67, 1.13)	0.89 (0.73, 1.09)
Madheshi ethnicity (ref: Pahadi)	1.58 (0.39, 6.41)	0.55 (0.13, 2.33)	1.14 (0.28, 4.68)	1.14 (0.57, 2.28)	1.31 (0.73, 2.35)
Mother's age at first marriage	0.96 (0.89, 1.04)	1.00 (0.98, 1.03)	0.99 (0.97, 1.02)	0.99 (0.97, 1.01)	0.99 (0.97, 1.00)
Final model					
Non-cephalic presentation	12.69 (7.96, 20.21)	N/A	1.52 (0.21, 10.95)	3.18 (1.87, 5.43)	4.87 (3.74, 6.34)
Preterm	1.91 (1.24, 2.93)	1.25 (0.12, 12.53)	2.05 (0.97, 4.34)	0.82 (0.57, 1.18)	1.44 (1.17, 1.77)
Facility delivery (ref: home delivery)	0.92 (0.61, 1.39)	N/A	0.94 (0.44, 1.99)	1.63 (1.26, 2.10)	1.51 (1.26, 1.82)
Maternal stature <145cm	1.25 (0.75, 2.08)	1.63 (0.16, 16.12)	2.02 (0.92, 4.45)	1.51 (1.11, 2.06)	1.43 (1.14, 1.78)
Newborn <2500g**	N/A	1.97 (0.25, 15.62)	5.11 (2.20, 11.89)	1.01 (0.77, 1.33)	N/A
Primiparous	1.27 (0.82, 1.95)	1.46 (0.14, 15.22)	1.01 (0.45, 2.24)	1.44 (1.10, 1.90)	1.34 (1.10, 1.63)
Mother literate	1.03 (0.65, 1.63)	N/A	0.87 (0.36, 2.11)	0.73 (0.54, 0.97)	0.77 (0.62, 0.95)

*This outcome includes any of the other four outcomes.
**Birth weight is not include for stillbirth-related outcomes.

Table 3.6: Association between multiple birth and adverse intrapartum-related fetal/neonatal outcomes

	Fresh stillbirth RR (95% CI)	**First day neonatal mortality RR (95% CI)**	**Early neonatal mortality RR (95% CI)**	**Signs of neonatal encephalopathy (early neonatal period) RR (95% CI)**	**Any of the above* RR (95% CI)**
Model 0					
Multiple birth	1.56 (0.50, 4.84)	5.81 (2.37, 14.24)	10.59 (6.46, 17.37)	2.28 (1.18, 4.43)	3.64 (2.57, 5.16)
Model 1 – preterm					
Multiple birth	1.18 (0.38, 3.71)	3.14 (1.26, 7.81)	6.16 (3.71, 10.23)	2.20 (1.12, 4.33)	2.94 (2.06, 4.21)
Preterm	2.24 (1.51, 3.32)	4.76 (2.80, 8.11)	3.99 (2.70, 5.90)	1.08 (0.80, 1.45)	1.64 (1.35, 2.00)
Model 2 - clinical care related					
Multiple birth	1.61 (0.52, 4.98)	6.17 (2.51, 15.15)	11.02 (6.71, 18.09)	2.22 (1.15, 4.29)	3.54 (2.50, 4.99)
Facility delivery (ref: home delivery)	1.09 (0.77, 1.56)	1.08 (0.64, 1.81)	1.18 (0.81, 1.70)	1.83 (1.46, 2.30)	1.53 (1.29, 1.81)
Received uterotonic during labor and delivery (ref: did not receive)	1.93 (0.63, 5.96)	2.98 (0.74, 12.08)	2.53 (0.82, 7.84)	0.53 (0.14, 2.10)	1.22 (0.63, 2.37)
Model 3 - maternal vs. fetal size					
Multiple birth	1.57 (0.51, 4.85)	N/A	5.50 (1.97, 15.35)	1.96 (0.90, 4.29)	3.59 (2.54, 5.07)
Maternal stature <145cm	1.52 (0.98, 2.37)	7.60 (0.48, 121.25)	3.86 (0.97, 15.36)	1.61 (1.08, 2.39)	1.45 (1.18, 1.79)
Newborn <2500g**	N/A	5.09 (0.46, 56.11)	6.93 (2.75, 17.52)	1.23 (0.92, 1.64)	N/A
Interaction term: maternal stature <145cm x newborn <2500g**	N/A	N/A	0.40 (0.08, 2.01)	0.79 (0.43, 1.47)	N/A
Model 4 - primiparity					
Multiple birth	1.60 (0.51, 4.96)	6.00 (2.43, 14.79)	10.91 (6.63, 17.95)	2.42 (1.25, 4.70)	3.77 (2.66, 5.33)
Primiparous	1.13 (0.77, 1.66)	1.20 (0.69, 2.10)	1.21 (0.81, 1.81)	1.51 (1.20, 1.91)	1.33 (1.12, 1.59)

Model 5 – Socioeconomic status					
Multiple birth	1.56 (0.50, 4.84)	5.41 (2.20, 13.27)	10.01 (6.11, 16.41)	2.20 (1.13, 4.28)	3.51 (2.48, 4.98)
Mother literate	0.99 (0.66, 1.48)	0.45 (0.23, 0.91)	0.54 (0.33, 0.87)	0.85 (0.65, 1.10)	0.83 (0.68, 1.01)
Madheshi ethnicity (ref: Pahadi)	1.98 (0.48, 8.12)	0.72 (0.17, 3.04)	1.40 (0.34, 5.74)	1.20 (0.60, 2.41)	1.45 (0.81, 2.62)
Age at first marriage	0.95 (0.88, 1.03)	1.00 (0.98, 1.03)	0.99 (0.97, 1.02)	0.99 (0.97, 1.01)	0.99 (0.97, 1.00)
Final model					
Multiple birth	1.22 (0.39, 3.83)	3.06 (1.22, 7.67)	5.91 (3.54, 9.85)	2.21 (1.13, 4.33)	2.97 (2.06, 4.28)
Preterm	2.19 (1.47, 3.26)	4.75 (2.76, 8.15)	3.94 (2.64, 5.86)	1.07 (0.80, 1.43)	1.63 (1.35, 1.98)
Facility delivery (ref: home delivery)	1.15 (0.79, 1.69)	1.23 (0.72, 2.11)	1.34 (0.91, 1.97)	1.80 (1.42, 2.28)	1.60 (1.34, 1.91)
Maternal stature <145cm	1.44 (0.90, 2.29)	1.18 (0.60, 2.33)	1.47 (0.94, 2.31)	1.52 (1.14, 2.01)	1.42 (1.14, 1.77)
Primiparity	1.16 (0.77, 1.76)	1.16 (0.64, 2.12)	1.17 (0.76, 1.80)	1.42 (1.12, 1.82)	1.30 (1.07, 1.57)
Mother literate	0.85 (0.55, 1.31)	0.52 (0.26, 1.06)	0.57 (0.35, 0.94)	0.72 (0.55, 0.94)	0.73 (0.59, 0.90)

*This outcome includes any of the other four outcomes.
**Birth weight is not include for stillbirth-related outcomes.

Table 3.7: Antenatal diagnosis and birth preparation among mothers who experienced non-cephalic birth

Non-cephalic birth		**n**	**%**
Number of singleton non-cephalic births		145	---
Mother aware prior to labor		42	29.0
Diagnosis and birth preparation		**n**	**% among those who knew**
Found out by*	Mother self exam	8	19.0
	Traditional healer	0	0
	Traditional birth attendant	5	11.9
	Auxiliary nurse midwives	4	9.5
	Doctor or nurse	3	7.1
	Ultrasound	25	60.0
Preparations made based on knowledge*	No preparation	14	33.3
	Consulted facility/doctor	10	23.8
	Planned to deliver at hospital/facility	18	42.9
	Made financial arrangements	7	16.7
	Had trained clinical personnel try to flip the baby	3	7.1

*Could provide multiple responses.

Table 3.8: Antenatal diagnosis and birth preparation among mothers who experienced multiple birth

Multiple birth		**n**	**%**
Number of multiple pregnancies		55	---
Mother aware prior to labor		20	36.4
Diagnosis and birth preparation		**n**	**% among those who knew**
Found out through physical assessment by*	Mother self exam	3	15
	Neighbor	1	5
	Traditional healer	0	0
	Traditional birth attendant	0	0
	Auxiliary nurse midwife	1	5
	Doctor or nurse	0	0
	Ultrasound exam	16	80
Preparations made based on knowledge*	No preparation	7	35
	Consulted facility/doctor	7	35
	Planned to delivery at a hospital/facility	11	55
	Made financial arrangements	4	20

*Could provide multiple responses

Chapter 4: Awareness and utilization of obstetric ultrasonography

Background

Ultrasonography is an invaluable medical diagnostic technology that allows for non-invasive imaging of internal organs and other tissues. In the context of obstetric use, ultrasound is used to confirm a pregnancy, to assess for multiple gestation, determine gestational age, monitor growth, detect fetal abnormalities, and diagnose placental or amniotic fluid issues. Even in settings where the equipment or operator skill does not allow for all of the aforementioned examinations to be completed, providing a basic exam can be beneficial in managing the antenatal period and also assessing potential risks during the intrapartum period. For instance, diagnosis of risk factors like multiple gestation, non-cephalic presentation, and preterm birth (via gestational age dating) could be greatly valuable in areas where access to tertiary-level care, or any facility-based care, is limited; the diagnosis may allow for timely birth preparation and subsequently, better health outcomes. An early exam between 10-14 weeks gestation allows for accurate gestational age dating and detection of abnormalities, while later exams (~18-22 weeks and/or ~30-34 weeks) allow for examination of fetal anatomy and growth.[1]

Ultrasound access is very limited in developing countries, particularly in rural settings. For example, in Nepal, a diploma medical radiology diagnostic course was started in 1988 at the main teaching hospital in Kathmandu (Tribhuvan University Teaching Hospital), producing its first graduates in 1990.[2] Approximately 150 radiologists (1 per ~185,000 population) reside in the country, and even this small cadre is largely concentrated in Kathmandu Valley and other major cities. In contrast, in the

U.S., there are 34,000 radiologists registered with the *American College of Radiology* in a population of approximately 319 million. Using these statistics, the U.S. has about 20 times more radiologists per capita than in Nepal.

To better understand access and utilization of obstetric ultrasonography in rural Nepal, we surveyed women soon after delivery to assess awareness of ultrasonography and utilization during their most recent pregnancy. We also conducted semi-structured interviews with providers in local birthing facilities to understand to what extent obstetric ultrasonography is integrated into antenatal care messaging.

Methods

This study was nested in the parent study. Data for this sub-study on ultrasound awareness and utilization were collected between March 2014 and March 2015 during the first home visit immediately after delivery. We asked questions regarding their knowledge of ultrasonography (what it is used for, from whom they heard about it) as well as their utilization of the diagnostic technology during their most recent pregnancy (for what, how much it cost). We first tabulated the responses to the survey questions, then conducted regression analyses, examining ultrasound use during pregnancy as an outcome of interest. We examined the following exposure variables: number of antenatal care visits made (0, 1, 2-4, ≥5 visits), maternal education (no formal education, 1-6 years, 7-10 years, ≥11 years), husband's education (no formal education, 1-6 years, 7-10 years, ≥11 years), and socioeconomic status, as represented by ownership of either *bari* (rainfed uplands) and/or *khet* (irrigated lowlands) (<1 katta, ≥1 katta, a katta being a unit of land

about 338 square meters in size) and housing structure (mainly thatch, grass, and/or branches, mainly wood, cement, and/or brick), maternal age (<18 years, 18-<35 years, ≥35 years), gravidity (first pregnancy, 1-3 previous pregnancies, ≥4 previous pregnancies), and sex of live born children prior to this delivery (no prior children, at least one live born son, no live born sons and 1-2 live born daughters, no live born sons and ≥3 live born daughters). We chose the aforementioned categories for the variable "sex of live born children" to understand whether preference for and/or pressure to have male children would impact use of ultrasonography.

We used the logistic regression model to calculate adjusted odds ratios. A *p*-value under 0.05 was considered statistically significant. We used Stata version 13.0 (Stata Corp.) for all analyses. Ethical approval was obtained at the Institutional Review Boards of Johns Hopkins Bloomberg School of Public Health in the U.S. and the Tribhuvan University Institute of Medicine in Nepal respectively.

Separately, we conducted semi-structured interviews with providers at all birthing centers in the study area (n=12) to understand protocols for complicated deliveries. We inquired specifically about their protocol for referring for antenatal ultrasonography during antenatal care visits. All birthing centers in Nepal provide free antenatal care as well as intrapartum care. In addition, the Safe Delivery Incentive Program has been in place since 2005; the program offers cash to women who attend four or more antenatal care visits and to women who deliver at a birthing center.[3]

Results

Between March 2014 and March 2015, 6182 recently-delivered women were interviewed; 75.8% of the interviews were conducted within 24 hours of delivery, an additional 8.8% within three days of delivery, and an additional 4.1% within the first week of delivery. The mothers were young (mean 23 years), and had a mean gravidity of 1.7. This was the first pregnancy for 28.5% of the women. 68.4% of the women had no formal education. See Table 4.1 for characteristics of women included in the study.

64.1% of the interviewed women had heard of ultrasound or "video x-ray" (a more commonly used term in this community). A large majority (72.4%) of those who had heard of ultrasound believed that the exams were for determining fetal position, and less than half of them reported that it was for assessing the baby's health, assessing the mother's health, and for fetal sex determination respectively. More than 50% of the women who had heard about ultrasound had heard from their families, neighbors, and/or friends, while only 12.7% heard from certified health practitioners (auxiliary nurse midwives, health assistants, community medical assistants, staff nurses) and 14.3% from MBBS doctors. (Table 4.2)

Among those who had heard of ultrasound, 42.3% had received an ultrasound exam during their most recent pregnancy; overall, 26.8% of all surveyed women received at least one ultrasound exam. Of those who received an exam, 62.0% only received one. Approximately a third of those who underwent an ultrasound exam reported that it was recommended by a physician to check on the mother's and/or baby's health. A little under a half reported checking on fetal position. 6.8% reported that they received the

exam to determine fetal sex. Half of the women received their most recent ultrasound exam within the study district (Sarlahi). Locations outside the study district included the cities with referral facilities to the west (Birganj, Parsa, 3-4 hour drive) and east (Janakpur, Dhanusa, 3-4 hour drive), and in India (10.1%, mostly in the cities immediately south of Sarlahi District in the Indian state of Bihar, 2-3 hour drive). The median cost of one ultrasound exam was 700 Nepali rupees (about USD 7, March 2015), IQR of 600-750, and range of 200-6400, with 7.1% above 1000 rupees (Table 4.3). Upon double-checking the outlier costs, we determined that they were, for the most part, exams conducted for fetal sex determination. The 7.1% is close to the 6.8% self-reporting fetal sex determination as the reason for their exam. Informal inquiries by our study staff to facilities and ultrasound clinics reported ultrasound costs to be 400-600 rupees.

The number of antenatal care visits and years of the woman's and the husband's education had a dose response relationship with odds of a woman receiving an ultrasound exam during her pregnancy. Higher educational attainment of the woman had a stronger association with odds of receiving an ultrasound exam than of the husband; 7-10 years of education had an aOR of 3.40 (95% CI: 2.74-4.23) for the women and an aOR of 1.84 (95% CI: 1.58-2.14) for their husbands, and ≥11 years of education had an aOR of 10.28 (95% CI: 5.55-19.04) for the women compared to 1.99 (95% CI: 1.47-2.68) for their husbands (reference: no formal education). Proxies for household income, in the form of land ownership and better housing construction, both had weak but statistically significant associations with receiving an ultrasound exam. A young mother (less than 18 years of age) had lower odds of receiving an ultrasound exam (aOR 0.72, 95% CI: 0.59-

0.90) than a woman 18 to <35 years of age. Using as reference the women who had at least one live born son prior to this pregnancy, those who had 1-2 live born daughters and no live born sons did not have increased odds of receiving an ultrasound exam, but those who had ≥3 live born daughters and no live born sons had statistically significantly increased odds of undergoing an ultrasound exam (aOR 1.55, 95% CI: 1.15-2.08). (Table 4.4)

Twelve birthing centers were identified in our study area, which encompasses approximately one-third of the entire district. None of these centers have ultrasound capacity, thus many women attend private clinics if receiving their ultrasound exams within the district. Messaging given during antenatal care visits regarding ultrasonography differed across birthing centers. Providers from three birthing centers (one primary health center, two health posts) stated that they refer everyone who comes in for an antenatal exam for an ultrasound exam. Providers from three other birthing centers (one primary health center, one sub-health post, one NGO-run facility) stated that they only refer if they suspect a risk factor (e.g. non-cephalic presentation, multiple birth, growth-restricted fetus). Many providers indicated that women usually comply to an ultrasound referral if they are notified that the providers suspect some abnormality, but do not otherwise. One of those providers explicitly indicated that they limit their referrals to those with suspected risk factors because of concerns about the financial burden for the patient in paying for an ultrasound exam. Providers from other birthing centers mentioned more vaguely that importance of ultrasound is conveyed to the mother or that they recommend ultrasound but not in a standardized manner. Providers from two

birthing centers expressed concerns toward the quality of ultrasonography conducted at a local private ultrasound clinic, one of them indicating that she has received sonograms from that clinic that are not of the uterus. The same clinic is run by an MBBS doctor based at one of the birthing centers; it appeared that he consistently refers his patients to his private ultrasound clinic.

Discussion

Obstetric ultrasonography is the gold standard tool for diagnosing everything from more simple-to-detect risk factors such as fetal non-cephalic presentation and multiple gestation to more complex cases such as congenital abnormalities. Despite such diagnoses having the potential to inspire appropriate careseeking, access in developing countries is still very limited. In our study area in the rural plains of Nepal, only 26.8% recently pregnant women received an obstetric ultrasound exam, and over half of them only received one exam. High maternal and paternal educational attainment respectively (proxy variables for household socioeconomic status), and those who had three or more live born daughters but no live born sons all had statistically significantly increased odds of receiving an ultrasound exam, while mothers <18 years of age had statistically significantly decreased odds.

Nepal has made great progress in reducing its neonatal and maternal deaths, meeting their Millennium Development Goals #4 and #5. With that said, in a country where stillbirths and neonatal and maternal mortality still remain high, improving diagnostic capacity for potential complications may be invaluable in further lowering

these rates via increasing birth preparation for risky pregnancies. Increasing access to ultrasonography in low-resource settings could prove to be greatly beneficial. Tertiary referral facilities can be difficult to reach in rural areas, due to distance, transport, and cost; waiting for referral to those locations from the first point of contact with the health system may cause fatal delays in care for risky conditions that could be diagnosed antenatally. Taking our study area as an example, the entire district (as of May 2015) with a population of approximately 800,000 people does not have a single facility with Cesarean section (C-section) capacity. The nearest Comprehensive Emergency Obstetric Care facilities, which by definition have C-section capacity, are located in Birganj and in Janakpur, both three-to-four hours away by car. While creating a cadre of fully trained radiologists will require substantial human and financial resource inputs into the medical education system in Nepal, training lower-level health workers to detect basic obstetric risk factors may be feasible, especially with ultrasound technologies becoming more affordable and portable.[4] The potential for remote radiologist interpretation of locally conducted ultrasound exams through telemedicine strategies could also leverage the limited number of radiologists for greater coverage. This will be discussed further in Chapter 5.

There have been various training programs exploring expansion of ultrasound use in low-resource settings. A Partners in Health program trained Rwandan non-radiologist physicians on a nine-week program. Their study included obstetric and non-obstetric scans, and showed 96% concordance between their and radiologist diagnoses. Among those who received obstetric scans, 43% of the patients had their pregnancy management

plan altered.[5] In South Africa, a controlled trial examined the effect of adding basic ultrasound services at a community-based midwifery unit, and witnessed reductions in referrals to higher-level facilities.[6] It is unclear, however, the sustainability and the long-term quality of such programs. Ultrasound has also been introduced in refugee camp settings.[7,8] In a camp on the Thai-Burmese border, local health workers were able to make accurate fetal anthropometric measurements after a three-month training period, thus improving gestational age dating.[8] Mothers attending those clinics reported the use of ultrasound as a way to have more safety during childbirth, with many expressing concerns about the position of the fetus.[9] There is an on-going multi-country (Pakistan, Kenya, Zambia, Democratic Republic of Congo, and Guatemala) cluster randomized trial exploring whether introduction of ultrasound in rural health clinics could improve pregnancy outcomes.[10] There are also groups addressing the ultrasound technology itself to determine if low-cost, easy-to-use machines can be developed to best meet the level of human resource available in the health systems of developing countries.[11]

Expansion of ultrasound use will require caution. Increased access in developing countries has led to misuse and overuse in some contexts. A study in Vietnam noted a trend in overuse of obstetric ultrasonography; in a survey of 400 women, the average number of scans during pregnancy was 6.6, with one fifth of the women having ten or more scans. The authors indicated that this was most likely driven by the facility's desire for extra revenue.[12] A similar issue of excessive use of ultrasound exams and the exams being a source of revenue was reported in a Syria study.[13] A Ugandan study also reported overuse; when obstetric scans of the studied hospital were categorized as appropriate and

inappropriate by the investigators ("appropriate" defined as a scan provided for specific medical reasons and for dating and screening for congenital abnormalities between 10 and 24 weeks, "inappropriate" defined as a scan for gestational age dating beyond specified time, routine monitoring of growth despite no intrauterine growth restriction indication, and repeat scans for inability to determine placental position), 53.4% of 232 obstetric scans were labeled as inappropriate.[14] In Botswana, in a clinic where the doctors were all expatriates, overestimation of the diagnostic power of the ultrasound machine was observed, with some patients believing that all abnormalities and complications may be detected through sonography.[15]

Ultrasound can also be used for fetal sex determination, which is illegal in some settings. Prenatal sex determination and sex-selective abortions are illegal in Nepal.[16] A survey conducted in Nepal by the Center for Research on Environment Health and Population Activities (CREHPA) noted that 57% of the surveyed women were aware of ultrasound technology, 11% had sought an ultrasound exam, and a quarter of those 11% did it for prenatal sex determination.[16] Not only does such use of ultrasound have implications for abortion rates and sex ratios, there are also potential consequences of incorrect assessment. A Nigerian study reported that some women who were told via ultrasound that their fetus is male but ended up having a female infant reported negative experiences like marital conflict, physical violence from their partners, and regret toward tubal ligation.[17] A Ghanaian study reported an accuracy of only 86.5% when detecting fetal sex via ultrasound.[18]

The issue of prenatal sex determination has discouraged the expansion of ultrasonography, especially in South Asia. In our study, 6.8% of women who received an ultrasound exam during their pregnancy stated that they sought the exam for fetal sex determination, but this rate may be lower than the true percentage due to social desirability bias. We also noted that mothers with three or more live born daughters and no live born sons in the family were more likely to seek an ultrasound exam during pregnancy, which may hint at plans for sex selective abortion. While sex selection is a legitimate concern that touches upon human rights and gender equality issues, we must also not dismiss the clinical benefit of obstetric ultrasonography over these concerns. It will be invaluable to educate providers on related issues and institute and enforce regulations regarding services provided by private sonography clinics, allowing sonographic technology to be used to better prepare women and their families for potential complications.

The strength of our study is the quality of the data; the data on maternal characteristics were collected during the time of the relevant pregnancy, and the data regarding knowledge and utilization of ultrasound were collected very soon after delivery. Because of the quantitative nature of a survey, we were not able to collect detailed qualitative data pertaining to perspectives of the community toward obstetric ultrasonography.

Conclusion

Despite potential clinical benefits of obstetric ultrasonography as a diagnostic tool, only about a quarter of pregnant women in rural Sarlahi District utilize or have access to the technology. 36% of all surveyed women had not heard of the technology before. We see in our data that ultrasonography for sex determination remains an issue in Nepal, but the health community should work actively toward addressing the issue while also promoting the legitimate clinical use of ultrasonography. Considerations need to be made as to how access can be increased in countries with limited human resource; task shifting for basic obstetric sonography may be feasible in areas with limited access.

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Tables

Table 4.1: Characteristics of women included in the study

	n	%	Mean (SD)
Number of ANC visits during pregnancy			
0	1081	17.5	1.6 (0.8)
1	812	13.1	
2-4	3816	61.8	
≥5	466	7.5	
Woman's education			
No formal education	4230	68.4	2.5 (4.1)
1-6 years	664	10.7	
7-10 years	957	15.5	
≥11 years	330	5.3	
Husband's education			
No formal education	2490	40.3	4.7 (4.6)
1-6 years	1379	22.3	
7-10 years	1703	27.6	
≥11 years	605	9.8	
Land ownership			
<1 katta*	1831	29.7	16.4 (31.1)
≥1 katta	4337	70.3	
Housing structure			
Mainly made of thatch, grass, and/or branches	4122	66.9	
Mainly made of wood, cement, and/or brick	2042	33.1	
Maternal age			
<18 years of age	520	8.4	23.3 (4.8)
18-<35 years of age	5492	88.8	
≥35 years of age	170	2.7	
Gravidity			
First pregnancy	1761	28.5	1.7 (1.7)
1-3 previous pregnancies	3605	58.3	
≥4 previous pregnancies	816	13.2	
Sex of previous children			
Had at least one live born son	2773	44.9	
No live born son, 1-2 live born daughters	1222	20.0	
No live born son, ≥3 live born daughters	246	4.0	
No previous live born children	1940	31.4	

*A unit of land about 338 square meters in size.

Table 4.2: Knowledge of ultrasonography among recently pregnant women

Question	Response	n	%
Have you heard of ultrasound / video x-ray before?	Yes	3962	64.1%
	No	2220	35.9%
What is it for? (can provide up to three responses)	Baby's health	1566	39.5%
	Mother's health	1224	30.9%
	Fetal position determination	2868	72.4%
	Fetal sex determination	1539	38.8%
From whom did you hear about it? (can provide up to three responses)	Family	2208	55.7%
	Neighbors / friends	2622	66.2%
	Traditional birth attendant / chamain*	178	4.5%
	Community Health Volunteer	196	4.9%
	Local doctor (not certified)	369	9.3%
	Auxiliary Nurse Midwife / Health Assistant / Community Medical Assistant / Staff Nurse	502	12.7%
	MBBS doctor	565	14.3%

*Chamains are individuals in the community not formally trained in health work who take on some child birth-related duties, such as cutting the umbilical cord and massaging the baby.

Table 4.3: Obstetric ultrasound utilization among recently pregnant women

Question	Response	n	%, among those who had heard of ultrasonography (n=3853)	%, Among all women interviewed (n=6072)
Received ultrasound exam during most recent pregnancy	Yes	1630	42.3%	26.8%
Question	**Response**	**n**	**%, Among those who received an ultrasound exam (n=1630)**	**%, Among all women interviewed (n=6072)**
Number of ultrasound exams received during the most recent pregnancy	0		---	73.2%
	1	1011	62.0%	16.7%
	2	398	24.4%	6.6%
	3	141	8.7%	2.3%
	4	61	3.7%	1.0%
	5	12	0.7%	0.2%
	≥6	7	0.4%	0.1%
Reason for having sought ultrasound exam	Advised by doctor	564	34.6%	9.3%
	For the baby's health	529	32.5%	8.7%
	For the mother's health	515	31.6%	8.5%
	To determine the position of the baby	784	48.0%	12.9%
	To determine fetal sex	111	6.8%	1.8%
Location where most recent ultrasound exam conducted	Within the district	819	50.2%	13.5%
	Birganj (3-4 hour drive)	238	14.6%	3.9%
	Janakpur (3-4 hour drive)	296	18.2%	4.9%
	Kathmandu (6-7 hour drive)	36	2.2%	0.6%
	Elsewhere in Nepal	55	3.4%	0.9%

	India	165	10.1%	2.7%
	Other	4	2.5%	0.1%
Cost of most recent ultrasound exam (in Nepali rupees, 1 USD = 104 Nepali rupees)	Median: 700			
	Mean: 776			
	% above 1000 rupees: 7.1%			
	IQR: 600-750			

Table 4.4: Association between maternal/household characteristics and receiving an ultrasound exam during pregnancy

	n	aOR
Number of ANC visits during pregnancy		
0	1081	Ref
1	812	1.48 (1.22, 1.79)
2-4	3816	1.91 (1.65, 2.21)
≥5	466	5.08 (3.72, 6.93)
Woman's education		
No formal education	4230	Ref
1-6 years	664	1.58 (1.31, 1.90)
7-10 years	957	3.40 (2.74, 4.23)
≥11 years	330	10.28 (5.55, 19.04)
Husband's education		
No formal education	2490	Ref
1-6 years	1379	1.38 (1.19, 1.58)
7-10 years	1703	1.84 (1.58, 2.14)
≥11 years	605	1.99 (1.47, 2.69)
Land ownership		
<1 katta*	1831	Ref
≥1 katta	4337	1.14 (1.01, 1.29)
Housing structure		
Mainly made of thatch, grass, and/or branches	4122	Ref
Mainly made of wood, cement, and/or brick	2042	1.23 (1.08, 1.39)
Maternal age		
<18 years of age	520	0.72 (0.59, 0.90)
18-<35 years of age	5492	Ref
≥35 years of age	170	0.80 (0.58, 1.12)
Gravidity		
First pregnancy	1761	0.76 (0.52, 1.10)
1-3 previous pregnancies	3605	Ref
≥4 previous pregnancies	816	0.95 (0.79, 1.14)
Sex of previous children		
Had at least one live born son	2773	Ref
No live born son, 1-2 live born daughters	1222	1.04 (0.89, 1.21)
No live born son, ≥3 live born daughters	246	1.55 (1.15, 2.08)
No previous live born children	1940	1.07 (0.75, 1.54)

*A unit of land about 338 square meters in size

Chapter 5: Validity of home-based sonographic diagnosis of obstetric risk factors by lower-level health workers

Background

The time of birth poses great health risks to both the fetus and the mother. Approximately 40% of fetal, neonatal, and maternal deaths occurs during the intrapartum period or on the day of birth.[1] This equates to about 2.3 million deaths per year that may be averted with proper care at birth. Intrapartum complications can occur to the healthiest of mothers and fetuses, yet there are several risk factors, such as non-cephalic presentation or multiple gestation, that can be detected in the antenatal period; early diagnosis may allow for appropriate birth preparation. Lawn et al. reported adjusted odds ratios (aOR) of neonatal/perinatal deaths, ranging from 6 to 15 for breech, 8 to 34 for other non-cephalic presentation, and 2 to 7 for multiple gestation in low- and middle-income countries.[2]

Based on epidemiologic evidence of high mortality and morbidity risk being associated with these risk factors, their early diagnosis and subsequent referral for care have been highlighted as key research priorities. The 2014 Lancet Neonatal Series listed as one of the newborn health research priorities for the post-Millennium Development Goals era "How can the accuracy of community health workers in detecting key most important high-risk conditions or danger signs in pregnant women be improved?"[3] This research question relates very closely to a top research priority previously listed by a group of experts to address birth asphyxia resulting from intrapartum-related complications: "Can community cadres of workers identify a limited number of high-risk

conditions / danger signs (e.g. multiple pregnancy, breech, short maternal stature, etc.) and successfully refer women for facility birth? What is the predictive value and cost effectiveness?"[4]

Non-cephalic presentation, multiple gestation, and placenta previa are few of the risk factors for intrapartum-related complications that can be detected prior to the start of labor, and all require ultrasonography for accurate diagnosis. Access to ultrasonography is limited in low-resource settings, due to human resource constraints, availability and cost of equipment, and proximity to facilities. Taking Nepal as an example, there are approximately 150 radiologists (1 per ~185,000 population) in the country, the vast majority concentrated in major cities. This equates to about one-twentieth of radiologists per capita available in the United States. Abdominal palpation, as another method of diagnosis, has shown high variability in accuracy. Studies reporting on the validity of the Leopold's maneuver, a palpation method used to detect the fetal position, report sensitivities ranging from 28% to 88%,[5-9] a large majority of these studies being conducted in developed countries with highly trained health providers.

Taking into consideration the value of ultrasonography to improve preventive care-seeking for adverse obstetric outcomes, we explored the feasibility of community-based ultrasound diagnosis of obstetric risk factors, using lower-level health workers with limited training. The objective of the study was to determine the validity of these health workers' ultrasound-based diagnosis of non-cephalic position, multiple gestation, and placenta previa. We also examined facility delivery rates and other intrapartum-related

health outcomes, comparing those who were diagnosed with a risk factor through our ultrasound study with their counterparts from neighboring communities who did not.

Methods

This substudy was nested in the parent trial and spanned from September 2014 to September 2015, enrolling pregnant women who were gestational age 32 weeks or more based on the date of last menstrual period (LMP). The LMP date is expected to be accurate within five weeks, as women in our community received five-weekly visits by the staff to identify pregnancies.

Three auxiliary nurse midwives (ANM) were selected to conduct ultrasound exams for this study. ANMs are a cadre of health providers who must have at least a 10th grade education and are trained in 18 months of basic midwifery skills. One of the three ANMs was also a certified Health Assistant. Health Assistant candidates also must have at least a 10th grade education, and a School Leaving Certificate with at least a second division pass level. They receive 36 months of basic science and clinical training. The ANMs received two one-week ultrasound trainings, one month apart, at the Tribhuvan University Teaching Hospital, located in the capital, Kathmandu. The training was led by the faculty of the Department of Radiology. The training consisted of a lecture on ultrasonography, demonstrations by radiologists, and practice on mothers who were at the clinic for antenatal exams, with permission obtained from the women prior to examination.

For the study, we sampled pregnant women from seven of the 34 Village

Development Committees (VDC, a geographic administrative unit) in which the parent study operates, as those VDCs were located along a major road and closer to our main field office, making them easier to access by motorcycle than the other VDCs. We also operated in four additional VDCs just for the months of May-July 2015, as the seven VDCs alone did not provide enough pregnancies to examine during the low birth season. A list of eligible women who were of gestational age 32 weeks or more was produced by our data center, on a specified week for one of the designated VDCs in which the ANMs were making the home visits. The ANMs visited the pregnant women on the list and consented and enrolled them in the study if they had not delivered yet. Once the list for a particular VDC was completed, the ANMs moved on to another VDC to begin exams on a new list of women who were gestational age ≥32 weeks. We estimated that the ANMs would rotate through the designated seven VDCs in a minimum of ten weeks, allowing them to return to the first VDC at around the time when there would be a new group of eligible mothers with gestational age ≥32 weeks. Women who had not delivered between the first and the subsequent time the ANMs visited a specific VDC and thus appeared on the eligibility list again were not given a second ultrasound exam.

A pair of ANMs conducted each ultrasound home visit. A private location in the house was identified where the woman could lie down (on a cot/bed if available, mat on a floor if not). One family member was permitted to accompany the woman during the exam, if desired. To eliminate contamination of results, the ANMs were blinded to each other's exams; one ANM entered the location where the exam was to be conducted, while the other waited outside, and vice versa when it was the second ANM's turn to conduct

her exam. Each ANM identified whether the pregnancy was single or multiple gestation, fetal position (cephalic, breech, transverse, or oblique), and placental position (no issue, low-lying/marginal/partial previa, complete previa, or cannot determine), and images that represented those diagnoses were saved on the ultrasound machine. They were also instructed to detect the fetal heartbeat as ancillary care, with instructions to refer the mother to a facility if the heartbeat was not detected. Having two ANMs make one visit allowed for the calculation of inter-rater reliability, but we did not have all three ANMs conduct exams on one mother, to be respectful of the participant's time and possible discomfort from lying down for the length of time required to complete three exams.

If at least one of the two ANMs detected fetal malposition and/or multiple gestation, the mother was instructed to make a visit to a birthing center to confirm the diagnosis. They were also told to make preparations to deliver at the nearest Comprehensive Emergency Obstetric Care facility, if possible, or at least a nearby birthing center, if not. Placenta previa is a more dire medical condition that needs to be managed prior to labor. Women with suspected placenta previa were notified of the possible diagnosis immediately following the exam, and on the same day, the ANMs sent the images taken of the suspected placenta previa case by e-mail to in-country gold standard readers based in Kathmandu. These gold standard readers were instructed to provide their diagnosis within one week of notification (in actuality, no assessment took longer than 24 hours of notification). The ANMs then returned to the household the next business day to notify the pregnant woman of the gold standard diagnosis. Women who had no danger signs detected received counseling on the importance of antenatal care

visits, birth preparedness, and facility-based deliveries. They were also provided a list of nearby birthing centers, strongly emphasizing that the ANMs not detecting danger signs did not preclude them from having a complicated delivery. As this study was conducted to assess the validity with which the ANMs could detect the risk factors, the referral messaging was provided with the caveat that the ANMs had received minimal training and that the pregnant women should seek additional care to confirm any diagnoses.

At the end of each business week, the images were downloaded onto a computer and sent to our data manager, who then uploaded the images onto a server. The images were de-identified by removing both patient and ANM information. We had two sets of gold standard assessors, thus each exam received a gold standard assessment twice: one set was reviewed by a team at the Johns Hopkins Hospital Maternal-Fetal Medicine Unit in Baltimore, Maryland, U.S. (one obstetrician and five obstetric ultrasonographers) and the other set was reviewed by two radiologists based at Tribhuvan University Teaching Hospital in Kathmandu, Nepal. The gold standard assessors were instructed to log on to the server and fill out an online form next to each set of images to make their diagnostic assessments.

The portable ultrasound machine used was the Sonosite Nanomaxx system, which was donated by the SonoSite Soundcaring Program, and a C60n (obstetric) probe. The program provides new or refurbished systems to communities in low-resource settings. The Nanomaxx weighs 2.7kg, and has the dimensions of 35.8 cm length x 20.8 cm height x 5.8 cm width. The machine was initially transported using a soft case provided by the manufacturer, but the study team later prepared a hard case lined inside with sponge to

better protect the machine during transport. The ANMs made their home visits on a shared motorcycle with the machine in hand.

The sample size was calculated using precision (the maximum difference between the sensitivity estimated by the study and the true sensitivity) of 0.10, alpha of 0.05, expected true prevalence of non-cephalic position in the mid-/late third trimester of 7%, and a target sensitivity of 90% We calculated a sample size of 500 women who needed to be examined by each ANM. However, since the ANMs conducted the home visits in pairs (ANM 1 and 2, ANM 1 and 3, ANM 2 and 3), we needed a total of 750 women in order for each ANM to conduct 500 exams.

We calculated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of diagnosis for each ANM against the gold standard diagnoses. We also calculated kappa statistics between each pair of ANMs to estimate inter-rater reliability.

We identified a comparison group from the parent study that included two neighboring VDCs that the ultrasound study did not operate in and three VDCs that we operated in minimally (nine, nine, and fifteen days of study operation in these VDCs respectively through the entire one-year study period), but excluding those who received an ultrasound exam from our study. We also excluded from the comparison group all women who delivered prior to 32 weeks gestation to match the ultrasound study's inclusion criterion. We compared facility delivery rates between women who received sonography from our study and the comparison group. We also examined the facility delivery rate and rate of adverse outcomes only among those who had a multiple or non-

cephalic birth, comparing the group that received a sonographic exam from the study and the comparison group. A similar analysis could not be conducted for placenta previa, as we do not have the diagnosis available in the comparison group.

Finally, we conducted a cost analysis, examining how much a life saved would cost under this sonography protocol. We calculated the total cost of operating a similar project over a five-year span and the number of fetal or neonatal deaths attributable to non-cephalic birth, multiple birth, or placenta previa, and divided the cost by the number of deaths potentially averted by ultrasonography.

We obtained ethical approval from the Institutional Review Boards of Johns Hopkins Bloomberg School of Public Health in the U.S. and the Tribhuvan University Institute of Medicine in Nepal respectively.

Results

815 women were enrolled in the study. A total of ten women were removed from the analysis: seven women examined on the first two days of the study (excluded as pilot data), two women whose images did not transfer properly from the machine to the computer, and one woman who terminated her exam early as she was uncomfortable lying down for an extended period of time. A final total of 805 women (1610 ANM exams) contributed to our analysis.

Technical issues

Between the start of the study in September 2014 and March 2015, the ultrasound machine was out of commission for a total of 17 weeks due to various hardware and software issues. Due to mechanical errors, the refurbished machine was replaced a total of four times. The errors were all thought to be manufacturing issues according to SonoSite's technical support team. The probe was also damaged once during transport (scratch to the probe surface), and was replaced. In mid-March, we received a new, non-refurbished machine from SonoSite, and the machine proceeded to function without any issues for the remainder of the study. The machine does not have a separate charger for the batteries, so the machine needed to be connected to a power source to charge batteries. To prevent damage from voltage fluctuations and surges that are common in rural Nepal, the machine was connected to the power source through a voltage stabilizer. In addition, in March 2015, we received from SonoSite a non-functioning ultrasound machine that could still be used as a battery charger. Thus, we were able to charge the batteries without directly connecting the machine that was in use for examinations to an unstable power source. The ANMs made home visits for the day with at least two fully charged batteries, often only needing one to cover a full business day's worth of home visits (5-6 mothers, or 10-12 ANM exams per day).

Diagnoses

At the time of completing this thesis (December 2015), the gold standard reviews by the readers from Tribhuvan University Teaching Hospital had not been completed.

Thus, we only present gold standard review data received from the readers at the Johns Hopkins Hospital.

The characteristics of the enrolled women are available on Table 5.1. Women had a mean age of 23.6 years and a mean gravidity of 1.7. A majority of women had no formal education (59.7%) and were of the Madheshi ethnic group (91.9%). Women enrolled in the study were diagnosed with the following by at least one ANM: 5.0% non-cephalic position, 0.8% multiple gestation, and 0.3% placenta previa. Of the exams that were reviewed, the gold standard reviewer selected "cannot determine" for the diagnosis for 0.1% of the exams for presentation and 0.9% for multiple gestation. The "cannot determine" rate for placenta previa was particularly high at 34%. The gold standard reviewers, in the comment section of their data collection form, frequently reported that the images inadequately captured the relationship between the placental edge and the internal os, but also that capturing such images is difficult in late pregnancy. We interpreted the "cannot determine" as a negative history for the three risky conditions (= not having that risk factor) and re-categorized the responses as such. At the time of birth, 2.2% and 0.6% of women gave non-cephalic and multiple birth respectively, based on maternal self-report.

Non-cephalic position. The kappa statistics for inter-rater reliability of diagnosing non-cephalic presentation were 1.00 (perfect agreement) between ANM 1 and 2 and ANM 1 and 3 respectively and 0.95 for ANM 2 and 3. Sensitivity ranged from 92.6 to 96.7% and specificity were in the high 90th percentiles or 100% for all ANMs, compared

against the gold standard reading. The PPV ranged from 92.6 to 100%, and the NPV were all nearly 100% (Table 5.2, a-c).

Multiple gestation. The kappa statistics for inter-rater reliability of diagnosing multiple birth were 1.00 between each pair of ANMs. The kappa statistics were all 1.00 (perfect agreement) with the gold standard for each ANM. When comparing the diagnoses to the true gold standard of maternal self-report of singleton or multiple birth, the ANMs and the gold standard reading agreed 100% with the self-report. (Table 5.3, a-e)

Placenta previa. ANMs were in agreement for the two placenta previa cases that were detected (one detected between ANM 1 and 2, and one detected between ANM 2 and 3). The gold standard was in agreement that these were either partial or complete placenta previa cases. Because of the small sample size, no further analysis was conducted for placenta previa.

Difference in birth outcomes by receipt of ultrasound exam

The birth outcome and facility delivery data for the entire cohort who partook in the ultrasound study will not be available until February 2016. We present the data available as of October 2015, for 584 out of 805 women.

The subpopulation who received the ultrasound exam from our study and the comparison group shared similar background characteristics, except for the preterm rate. This can be attributed to the ANMs reaching the home after some women had delivered

already. However, no statistically significant difference in preterm rates was seen among those who experienced a non-cephalic or multiple birth.

We saw no statistically significant difference in the self-reported non-cephalic or multiple birth rates or the facility delivery rate between the ultrasound and comparison group. Among those reporting either a non-cephalic or multiple birth, those receiving the intervention had a 94.4% facility delivery rate (17 out of 18) and those in the comparison group had a 61.1% facility delivery rate (24 out of 40) (p=0.043). Rates of adverse outcomes were lower in the intervention group when examining only those who had either a non-cephalic or multiple birth; none of the adverse outcome rates were statistically significantly different, but the study was not powered to detect a difference. When aggregating the adverse outcomes of fresh stillbirth, early neonatal mortality, and neonatal encephalopathy, and aggregating the exposures of non-cephalic and multiple birth, we observed a non-statistically significant lower rate of adverse outcomes among those who received an exam: 11.8% (2 out of 18) vs. 33.3% (10 out of 30) (p=0.103). (Table 5.4) Of the two adverse outcomes reported in the intervention group, one happened at a facility and the other occurred at home. In the comparison group, seven occurred at home and three at a facility.

Of the two placenta previa cases that were diagnosed, one resulted in a fresh stillbirth and another resulted in a maternal and fetal death.

Cost analysis

The logistical difficulties we had during our study put into question the feasibility of home ultrasound visits for future application. In light of that, we conducted this cost analysis using the hypothetical of a facility-based program. We assume that personnel costs would be subsumed by government salary and excluded transport costs for this reason. We assumed one ultrasound machine could cover a catchment area of 100,000 population, or 3000 births per year or 15000 births per five-year span. We estimated the cost of a refurbished machine (with a five-year warranty) to be 9500 USD (6000 USD for machine for global health buyers, 3500 USD for the probe), ultrasound gel for 15000 exams to be 375 USD (40 exams per bottle, 1 USD per bottle), and a two-week training to be 480 USD, for a total of 10355 USD. Using the Nepal DHS 2011 estimate of 37 intrapartum stillbirth or early neonatal death per 1000 pregnancies, 555 perinatal deaths are expected among the 15,000 births. Using the risk ratio of 7.09 and prevalence of 2.2% for non-cephalic presentation and risk ratio of 3.64 and a prevalence of 1.0% for multiple gestation, as taken from Chapter 3, we estimated 14% (or 78) of the perinatal deaths to be attributable to non-cephalic or multiple birth. As we do not have population-level data on placenta previa, we used the placenta previa incidence reported in a systematic review of 12.2 cases per 1000 pregnancies in the Asian region[10] and a reported perinatal mortality rate among placenta previa cases of 447 per 1000 live births from an Ethiopian hospital-based study.[11] We would then expect 82 placenta previa cases resulting in perinatal mortality, per 15000 pregnancies. Combining the perinatal deaths attributable to non-cephalic birth, multiple birth, and placenta previa, a maximum of 160 pregnancies may be

saved from a perinatal death with early diagnosis, a cost of $65 per life saved. This cost-benefit calculation makes a generous assumption that all diagnosed lives would be saved. However, it also does not take into account the potential disability life years saved by preventing morbidities from intrapartum-related complications or from the unintended benefit of referring preterm births to a facility, and also by preventing maternal mortality or morbidity. Maternal mortality was not examined due to the small number of cases. We also expect more affordable ultrasound machines to be available for facility-based use.

Discussion

We determined in our study that lower-level health workers can accurately conduct obstetric ultrasound exams to detect basic risk factors, with merely two weeks of training. The diagnosed risk factors were low in prevalence, but high in risk; early detection can potentially alter care-seeking behavior and subsequent health outcomes for those with these risk factors. There is an on-going multi-country (Pakistan, Kenya, Zambia, Democratic Republic of Congo and Guatemala) cluster randomized trial that is exploring whether introduction of ultrasound in rural health clinics could improve pregnancy outcomes.[12] In a country with a dearth of trained radiologists, our findings show great potential for task shifting. Other studies have also explored task shifting to non-radiologist clinicians, and found positive results.[13-16]

In our analysis, we re-categorized diagnoses that gold standard reviewers recorded as “cannot determine” as not having the risk factor, especially in light of the known low prevalence of these risk factors. While the rates at which the gold standard

reviewers reported “cannot determine” for multiple gestation and non-cephalic presentation were negligible, the rate for placenta previa was particularly high, at 34%. This could be attributed either to the skill level of the ANMs and/or the general difficulty of adequately imaging the placenta and the internal os in late gestation. In the U.S., trans-vaginal ultrasound would be conducted if the trans-abdominal ultrasound exam cannot adequately determine the placental location. Therefore, the percentage of “cannot determine” we reported may not be particularly high. So while both sets of gold standard examiners agreed with the two placenta previa cases identified by the ANMs (the Tribhuvan University Teaching Hospital assessment for these two cases were received at the time of the actual ANM exam for referral purposes), we cannot determine using only still images whether other placenta previa / low-lying placenta cases were missed by the ANMs.

While we only explored the feasibility of diagnosing three obstetric risk factors, there is the potential to train ANMs to conduct other diagnostic tasks as well. For instance, accurate gestational age dating is critical in reducing the large burden of neonatal death attributable to preterm birth, the leading cause of neonatal death. In one study conducted in a refugee camp on the Thai-Burmese border, local health workers were able to make accurate fetal anthropometric measurements after a three-month training period, allowing for high quality gestational age dating.[16]

Task shifting obstetric ultrasonography to lower-level health workers in a regulated setting may also prove better than proliferation of unregulated ultrasound clinics. In India, prenatal sex selection has been illegal since 1996, yet there is minimal

enforcement, as most of the illegal sex determination occurs in unregulated private clinics.[17] We noted during our interactions with birthing center staff that there are private clinics in our study area that are notorious for providing poor quality images. One facility staff member indicated that they had received a sonographic image of another organ from a private clinic run by an MBBS doctor instead of an image of a uterus. The same doctor was a physician at a local birthing center, and it appeared that he was referring the patients from this public, no-fee birthing center to his for-fee private ultrasound clinic. While this is only one example, there are considerations that need to be taken into account regarding the quality of exams being conducted by non-radiologist clinicians under these unregulated circumstances, as well as concerns private ultrasound clinics introduce, such as the conflict of interest demonstrated in this example or access to illegal fetal sex determination. Other studies from developing countries have also reported excessive provision of ultrasound exams, driven by the clinic's desire for extra revenue.[18,19]

Introduction of ultrasonography must be done with care, as there is potential for misuse, like illegal fetal sex determination. Prenatal sex determination and sex-selective abortions are illegal in Nepal.[20] While the rate of obstetric ultrasonography use is still generally low in Nepal, we noted in Chapter 4 that 7% of women who had received ultrasonography in our community reported fetal sex determination as the reason for receiving an exam, and another survey conducted in Nepal reported a quarter of women who had received ultrasonography as having done so for fetal sex determination.[20] Such use of ultrasound has implications for abortion rates and potential adverse maternal health

outcomes if abortions are handled improperly. There are also potential consequences of incorrect assessments. One study from Nigeria indicated that incorrect fetal sex determination (diagnosed as the fetus being male, but actually giving birth to a female infant) contributed to negative experiences like marital conflict, physical altercation with their partners, and regret toward tubal ligation.[21] In one study from Ghana, the reported accuracy of fetal sex determination was only 86.5%.[22] Even in situations where the ultrasound technology itself was being used appropriately, there are reports of poor clinician-to-patient interactions or maternal anxiety related to the use of ultrasound.[22,23] In Botswana, in a clinic where the doctors were all expatriates, there was limited communication about the procedure and the findings to the patients. The darkness of the examination room triggered fear and anxiety in many. There was also an issue with overestimating the diagnostic power of the ultrasound machine, with some patients believing that all abnormalities and complications will be detected through sonography.[24]

We experienced multiple technical issues with the ultrasound machine during our study. There may be fewer issues with the use of smaller mobile-based ultrasound devices. However, we consciously avoided the use of a mobile-based device for this study, as we did not want the ANMs' diagnostic accuracy to depend on external factors like the visibility of a small screen. However, with confidence in their skill, it may be feasible to utilize a much smaller piece of equipment. The robustness of such equipment in low-resource settings will need to be tested prior to scale-up. Maru et al. highlight five criteria for x-ray or ultrasound use in low-resource settings: a) be robust in harsh environmental conditions, b) function reliably in environments with unstable electricity,

c) minimize radiation dangers to staff and patients, d) be operable by non-specialists, and e) produce high-quality images required for accurate diagnosis.[25] Several groups are working on the development of low-cost, easy-to-use machines to best meet the level of human resources available in developing countries.[26]

Diagnosis is only a small component of a woman or a household's decision to seek care. As it will be reported in Chapter 7, there are numerous barriers to seeking care like distance to a facility and cost of care and/or transport. These barriers would even be higher among women who are referred to more distant tertiary facilities, like women diagnosed in this study, since lower-level facilities will not have staff or equipment to handle these conditions safely.[27] Several interventions have been tested to lower some of these hurdles for care-seeking. For instance, several countries, including Nepal, have instituted a cash transfer system for facility-based deliveries.[28] While facility delivery rates have gone up in Nepal since the institution of the program, it unevenly benefits more those who are in the wealthier socioeconomic stratum than those who need the financial support the most.[29] A systematic review on cash transfer systems to increase facility-based deliveries have also reported that there is insufficient evidence thus far on the impact of these programs on health outcomes.[30] Perceptions of severity of a health condition can also affect the decision to seek care.[31-34] A qualitative study in Kenya reported that not having had complicated deliveries in the past deterred women from seeking care.[35] This highlights the importance of understanding community perceptions toward obstetric risk factors, as we will explore in Chapter 6.

In comparing those who received an ultrasound exam through our study versus those who did not, several points should be noted. One, the comparison group was not randomized. While background characteristics were similar, the geographic areas are expected to have differences, such as access to roads and facilities. Second, the intervention group did not capture all preterm births. Third, the sample size for the entire study was powered to detect the target sensitivity for validating whether ANMs can accurately diagnose women, and not powered to detect any differences in health outcome between those who did or did not receive an ultrasound exam in our substudy. Thus, our findings regarding the impact of the sonographic exams on facility delivery rates and health outcomes should be interpreted with caution and should not be accepted as conclusive. A larger, randomized trial is needed to have better evidence regarding the impact of obstetric ultrasonography on inspiring referral and subsequently improving health outcomes.

Conclusion

Our study demonstrated the feasibility for task shifting to lower-level health workers conducting ultrasound-based diagnostics to accurately identify women with high obstetric risk in low-resource settings. While inconclusive due to small sample size, we saw lower adverse outcome rates among those diagnosed with a risk factor by ultrasound. More data are needed to determine if in fact antepartum ultrasound diagnosis of selected high-risk obstetrical factors contributes to improved health outcomes in these settings.

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Tables

Table 5.1: Characteristics of the pregnant women in the study

	Enrolled in ultrasound study (n=815)	**Comparison group (n=1037)**
Gestational age at exam		
Mean (SD)	40.0	39.5
<37 weeks	6.2%	13.8%
Age		
Mean (SD)	23.6	23.2
<18 years old	7.4%	8.7%
18-<35 years old	89.8%	89.1%
≥35 years old	2.9%	2.2%
Gravidity		
Mean (SD)	1.7	1.6
0	31.0%	29.4%
1-3	56.3%	59.3%
≥4	12.7%	11.3%
Parity		
Mean (SD)	1.4	1.5
0	33.3%	32.8%
1-3	57.5%	58.5%
≥4	9.1%	8.7%
Education		
No formal education	59.7%	66.7%
1-9 years	24.9%	21.5%
≥10 years	15.4%	11.8%
Ethnicity		
Madheshi	91.9%	93.9%
Pahadi	8.1%	6.1%

Table 5.2: Inter-rater reliability and validity of diagnoses, non-cephalic position

a. Inter-rater reliability

	ANM 1 vs. 2		**ANM 2 vs. 3**		**ANM 1 vs. 3**	
	Cephalic	Non-cephalic	Cephalic	Non-cephalic	Cephalic	Non-cephalic
Cephalic	249	0	261	0	257	0
Non-cephalic	0	19	1	9	0	8
	K = 1.00		K = 0.95		K = 1.00	

K = kappa

b. Comparison with gold standard reading

	ANM 1		**ANM 2**		**ANM 3**	
Gold standard	Cephalic	Non-cephalic	Cephalic	Non-cephalic	Cephalic	Non-cephalic
Cephalic	504	2	511	0	518	1
Non-cephalic	2	25	1	29	1	16

c. *Validity compared against gold standard reading*

	ANM 1	**ANM 2**	**ANM 3**
Sensitivity	92.6	96.7	94.1
Specificity	99.6	100.0	99.8
Positive predictive value	92.6	100.0	94.1
Negative predictive value	99.6	99.8	99.8

Table 5.3: Inter-rater reliability and validity of diagnoses, multiple gestation

a. Inter-rater reliability

	ANM 1 vs. 2		**ANM 2 vs. 3**		**ANM 1 vs. 3**	
	Single	Multiple	Single	Multiple	Single	Multiple
Single	268	0	269	0	262	0
Multiple	0	0	0	2	0	3
	K = N/A*		K = 1.00		K = 1.00	

K = kappa

*Kappa value cannot be calculated without having at least two cells with values

b. Comparison with gold standard reading

	ANM 1		**ANM 2**		**ANM 3**	
Gold standard	Single	Multiple	Single	Multiple	Single	Multiple
Single	530	0	539	0	531	0
Multiple	0	3	0	2	0	5

c. *Validity compared against gold standard reading*

	ANM 1	**ANM 2**	**ANM 3**
Sensitivity	100	100	100
Specificity	100	100	100
Positive predictive value	100	100	100
Negative predictive value	100	100	100

d. Comparison with maternal self-report after delivery

	ANM 1		**ANM 2**		**ANM 3**		**Gold standard readers**	
Maternal self-report	Single	Multiple	Single	Multiple	Single	Multiple	Single	Multiple
Single	530	0	539	0	531	0	1602	0
Multiple	0	3	0	2	0	5	0	10
	K = 1.00		K = 1.00		K = 1.00		K = 1.00	

K = kappa

e. *Validity compared against maternal self-report*

	ANM 1	**ANM 2**	**ANM 3**	**Gold standard**
Sensitivity	100	100	100	100
Specificity	100	100	100	100
Positive predictive value	100	100	100	100
Negative predictive value	100	100	100	100

Table 5.4: Difference in birth-related outcomes between those enrolled and not enrolled in the ultrasound study

	Enrolled in ultrasound study		**Comparison group**		***p***
	n	**%**	**n**	**%**	
% non-cephalic birth at delivery, self-reported	539	1.9	967	2.7	0.310
% multiple birth, self-reported	557	1.4	1010	1.4	0.936
Preterm rate*	545	6.2	997	13.8	<0.001
Facility delivery rate	557	63.3	1007	59.5	0.150
Outcomes among those who reported non-cephalic birth					
Preterm rate	10	30.0	25	16.0	0.350
Facility delivery rate	10	90.0	26	53.9	0.043
Fresh stillbirth / early neonatal mortality	9	11.1	23	21.7	0.489
Signs of neonatal encephalopathy	9	11.1	17	17.7	0.660
Any of the above	9	22.2	22	38.4	0.445
Outcomes among those who reported multiple birth					
Preterm rate	8	25.0	12	50.0	0.264
Facility delivery rate	8	100.0	12	83.3	0.224
Fresh stillbirth / early neonatal mortality	8	0.0	13	15.4	0.243
Signs of neonatal encephalopathy	8	0.0	7	0.0	---
Any of the above	8	0.0	9	22.2	0.156
Outcomes among those who reported either non-cephalic or multiple birth					
Preterm rate	18	27.8	35	28.6	0.952
Facility delivery rate	18	94.4	36	61.1	0.010
Fresh stillbirth / early neonatal mortality	17	5.9	35	20.0	0.186
Signs of neonatal encephalopathy	17	5.9	23	13.0	0.455
Any of the above	17	11.8	30	33.3	0.103
Outcomes among those who reported NEITHER non-cephalic or multiple birth					
Preterm rate	509	5.7	922	13.2	<0.001
Facility delivery rate	521	61.2	930	57.7	0.195
Fresh stillbirth / early neonatal mortality	520	3.1	925	2.4	0.426
Signs of neonatal encephalopathy	490	3.1	823	4.3	0.275
Any of the above	500	5.6	838	6.4	0.534

*Preterm rates only include ≥32 weeks gestation due to study inclusion criterion.

Chapter 6: Care-seeking / care-giving behavior and perceptions of etiologies and consequences associated with non-cephalic presentation

Background

Globally, 2.7 million neonatal deaths[1] and 2.6 million stillbirths[2] occur annually, a large majority of them in low- and middle-income countries. Of those, 1.2 million infants die during labor and an additional 1 million die within the first day of life, mostly due to insults during labor and delivery.[3] A focus on the intrapartum period, during which risk of death is highest in one's lifetime, holds great potential to prevent not only fetal, neonatal, and maternal mortality, but also impairments and morbidities, such as consequences of neonatal encephalopathy[4] and preterm birth.[5,6] The 2014 Lancet Every Newborn Series [7] highlights the potential return on investing in improvements in intrapartum care. Many women around the globe do not have a skilled birth attendant present at delivery, making labor and delivery all the more risky; approximately 40% of women worldwide still deliver at home.[7] While all women would benefit from a facility-based delivery, it may be valuable to identify and refer, prior to the beginning of labor, women who may be at particularly high risk of complications. For instance, fetuses born in non-cephalic presentation (the fetus presenting with a body part other than its head first, e.g. breech) have heightened risk of stillbirth and neonatal death (Chapter 3).[3,8-10]

It is critical to minimize the time it takes for a woman with an intrapartum complication to receive care. One barrier is the failure by the woman and/or the decision-maker to perceive the risk of a dangerous health condition. Although existing epidemiologic data report high mortality and morbidity risk associated with non-cephalic

birth, there are few data available on perceptions and care-seeking associated with non-cephalic presentation. We describe the circumstances surrounding labor and delivery of women who recently experienced a non-cephalic delivery in rural Sarlahi District, Nepal, and highlight existing perceptions and care-seeking behavior specific to non-cephalic presentation. Through interviews with women who had a non-cephalic delivery in the past year and with female decision-makers of their households, and focus groups with women in the community, we sought to identify the barriers to care-seeking among women who are diagnosed with a non-cephalic fetus or are experiencing a non-cephalic delivery.

Methods

This study was conducted from November 2014 to January 2015. The author had resided in Sarlahi District for ten months prior to the start of the study, and a total of fifteen months when including a previous stay. The study was nested in the parent study. As part of routine follow-up of recently delivered women enrolled in the trial, women were asked about fetal presentation (which part of the fetal body presented first during delivery). For this qualitative study, we used those responses to identify women who reported a singleton non-cephalic delivery between two and twelve months prior to the time of interview. An interview guide was created with questions organized into the following major themes: background characteristics of the interviewee, conditions during pregnancy, conditions during labor and delivery, and non-cephalic presentation. The interview guide was first created in English, then translated into Nepali with input from

the local staff, then translated into Maithili, the local language used most commonly in the study area. The Maithili guide was also verbally back-translated into English to check for errors. The author had basic command of the Nepali language, but not Maithili.

To obtain the individual perspectives of the woman who delivered the baby (referred to as the "woman" hereafter) and a female decision-maker in the household (referred to hereafter by her relation to the woman, e.g., "mother" or "mother-in-law"), we opted to conduct independent, simultaneous interviews with these two individuals in a single household. Eight pairs of these interviews were conducted by local female staff trained in qualitative data collection. The eight pairs were selected based on location of delivery and pregnancy outcomes: two pairs of home deliveries with an infant who survived at least until 28 days after birth, two pairs of home deliveries that resulted in either a stillbirth or an early neonatal death, and two pairs each of the above, among facility deliveries. Participants were interviewed at their homes in separate rooms. The author was present at the home but did not sit in on the interviews to minimize participant reactivity. The author conducted debriefings with the interviewers to summarize content, highlight common or discordant themes between the respondents, revise questions for comprehension, and discuss any difficulties. Randomly selected portions of the recordings from the first four pairs of interviews were reviewed to identify issues such as method of questioning, tone of voice, and probing. Also, the interviews were temporarily halted after the first two pairs to await the full English translation of the transcripts. The author identified key issues based on the full translations and debriefed with the interviewers before proceeding with subsequent interviews.

After eight paired interviews, we determined that conducting two interviews per household did not provide significant additional insight, and that the decision-maker often provided more relevant information. Thus, subsequent interviews were conducted solely with the primary female decision-maker if available, and if not, with the woman herself. We attempted to keep a similar balance of home/facility delivery and alive/dead infant, as mentioned above. We continued debriefings following each interview and conducted interviews until saturation was reached, for a final total of 34 interviews from 26 households. Male decision-makers were not interviewed due to concerns of cultural appropriateness of our interviewers (married women in their early- to mid-twenties) interviewing male adults.

In order to better understand how the general community perceives the issue of non-cephalic presentation, we also conducted two focus group discussions (FGD) with younger women (inclusion criterion: at least two children, with at least one under five years of age) and with older women (inclusion criterion: at least one grandchild) in the community respectively. These audio-recorded discussions focused on general pregnancy care, fetal presentation, and preferences for delivery location. Debriefings with the facilitator and the notetaker were also conducted after each FGD. We received informed verbal consent from all individuals participating in the interviews and the FGDs.

Our study area consists predominantly of one ethnic and religious group. All eligible women belonged to the Madheshi ethnic group (a group that originated in north India and migrated into the southern plains of Nepal), and of the 26 families interviewed, 25 were Hindu and one was Muslim. Interviews and FGDs were conducted in Maithili,

the language spoken by Madheshis. The interviewers/facilitators were locally resident Madheshi women with high school education, and spoke Maithili and Nepali fluently. The interviewers received a one-month training on qualitative data collection from Transcultural Psychosocial Organization Nepal, an NGO that supports psychosocial and mental well-being of vulnerable subpopulations. The content of the training included principles of qualitative methods, conduct of in-depth interviews and focus groups, consent and research ethics, probing, rapport building, and transcription. The interviewers also conducted practice interviews and focus groups with local women on non-sensitive subjects, and the recordings and transcripts were reviewed by the trainer and discussed with the interviewers.

IDI and FGD recordings were first transcribed from Maithili to Nepali by the interviewers/facilitators themselves. The transcripts were then sent to Nepali translators based in Kathmandu for translation from Nepali to English. For the first four interviews, the translations were checked page by page for accuracy against the Nepali transcripts. For all other translations, the author met with the qualitative team coordinator for any clarification after one read-through of the translations. Recordings, transcripts, and translations were all de-identified, and labeled with an interview number.

The transcripts underwent an iterative coding process using Atlas.ti. The codebook contained thematic codes reflective of the major themes in the interview guides, then emergent codes were added as transcripts were reviewed. All transcripts were coded and reviewed a second time. To organize the coded data, a matrix was created with major themes in rows and the individual interviews in the columns. Findings arising from each

interview were summarized in the matrix, and representative quotes were extracted. Findings were compared across the interviews for common or divergent perspectives under each theme. For main conclusions drawn from the interviews, disconfirming cases were sought for quality assurance, and the findings were appropriately revised based on that process.

We obtained ethical approval from the Institutional Review Boards of Johns Hopkins Bloomberg School of Public Health in the U.S. and the Tribhuvan University Institute of Medicine in Nepal respectively.

Results

We first interviewed eight women and their respective decision-makers: six mothers-in-law, one biological sister who was also a sister-in-law by marriage, and a grandmother-in-law (the woman's husband's grandmother). The subsequent one-per-household interviews consisted of six women (the ones who experienced the non-cephalic birth), six mothers, five mothers-in-law, and one sister-in-law. The women who gave the birth ranged from age 16 to 35 at the time of interview (median 23 years) and the number of previous pregnancies ranged from 0 to 5 (median 2). Age at first marriage ranged from 13 to 18 years (median 16 years). Only four of the 26 women had any education, of whom only one had completed high school. For the four focus groups, both of the younger women focus groups had eight attendees (median age 24 and 25 respectively), and the older women focus groups had eight and seven attendees respectively (median age 58 and 50 respectively).

Conditions during labor and delivery related to non-cephalic presentation

Most families described labor complications due to the fetus getting "stuck." Many mentioned the fetus hanging by the neck, with the body or the head getting stuck after presentation of only the fetus' lower extremities. One woman compared the baby being stuck to a noose. Another described:

> The whole of the heel of one foot came out while we were going to [a government health facility]. The baby's foot stretched inside like our foot would stretch if our foot had slipped inside a pothole in the road. It would stretch if we tried to take it out with our hands. It would not come down. I could feel it all. – woman, age 22

The same woman added that months after delivery, she still felt so much pain that it felt like the fetus was still stuck. Her grandmother-in-law described that "if the baby were normal [in cephalic position] it would just slip and drop down."

Many households described the woman receiving injections to induce labor following such obstruction. The content of the injections was never identified, but several women indicated that they provided strength and energy for delivery. One mother-in-law indicated their purpose as widening the vaginal opening. One woman reported receiving four injections just in the intrapartum period to address the obstruction. Focus groups indicated that receipt of injections during labor was common, regardless of fetal presentation. Both in FDGs and IDIs, women stated that injections are given after labor pain begins, which differs from the clinically recommended uterotonic injections given during the third stage of labor to prevent postpartum hemorrhage. Episiotomies, known

locally as a “small operation” to distinguish it from the “big operation” of a Cesarean section (C-section), were also very common.

Just over half of the interviewees had a home delivery, and possibly harmful practices were described. In multiple cases, birth attendants / family members pressed on the woman’s stomach to aid delivery, and in other cases, birth attendants and family members stuck their hands into the vagina to pull the fetal head out. Another woman described her aunt pressing on her stomach when the contractions stopped after half of the fetus’ body was delivered. One mother reported that she pulled the fetal leg in a way that significantly increased her daughter’s pain.

Poor practice was not limited to home deliveries. In one case, a woman and her mother-in-law eagerly and angrily described conditions during delivery at a tertiary health care facility, with the hope that our study staff could play a role in addressing these issues. The woman described the nurses as having “pulled my baby like pulling old stuff from a sack.” A doctor later reprimanded the nurses, and following delivery, referred the infant to Kathmandu, where the baby subsequently died. The same woman was also only referred from the primary facility to the tertiary facility for fetal malpresentation in the morning after being admitted the previous evening. The mother-in-law angrily reported that if they had been told in the evening about the malpresentation, they would have sought higher level care sooner.

Several individuals reported an arduous care-seeking process either for the mother during labor or for the newborn after birth, being taken from one facility to another in an area that would take multiple hours on poorly paved or unpaved roads by motorized

vehicles, and longer if by ox cart. One was referred for non-cephalic presentation from the nearest clinic to a tertiary facility. The family made a stop in the district capital about an hour's drive away to receive an ultrasound exam to confirm the fetal position, then to a facility in India that was another hour away. A few families sought care for their infants in one or more facilities in the area before proceeding to Kathmandu (a minimum six hour drive, often longer) for higher-level care.

Antepartum diagnosis

Only two women knew through an antepartum ultrasound exam that their fetuses were in non-cephalic position prior to labor. A third woman received an ultrasound exam in the eighth month for the purposes of fetal sex determination. Her mother-in-law was aware that fetal position could be detected through ultrasonography, but they were not told anything about it by the doctor. Only a few women acknowledged ultrasonography as a method of identifying the position of the fetus. A few interviewees expressed puzzlement over questions regarding antepartum diagnosis of fetal presentation, as they did not understand how they could have detected the position when the fetus was still inside the womb and thus not visible. Some women suspected just from the physical feel during pregnancy that their fetuses may be breech, and several were diagnosed inaccurately or possibly diagnosed too early in pregnancy. One woman said she was falsely told by a traditional birth attendant that she had twins, and others described traditional birth attendants mistaking the fetal buttocks for the head right around the start of labor or not noticing that the fetus was breech until well into labor. One woman noted

that a village midwife (*hatkini*) put her hand into the vagina at the beginning of labor and said that the baby was in the correct position, and the woman added, "So we don't know how the baby got to be in the incorrect, upside-down position." One woman had been told during an antenatal check-up with a village "doctor" (not a certified doctor) that she had a non-cephalic fetus, but was subsequently told the contrary at a health facility. Based on that information, she was not taken by her family to a health facility at the time of delivery. In the FGDs, ultrasonography and a physical exam (by a doctor, local health attendant, etc.) were mentioned as possible ways of diagnosing non-cephalic position in the older women's focus groups, although the latter was deemphasized in the younger women's focus groups. In one of the older women's focus groups, many women expressed awareness of ultrasonography as a tool for diagnosing fetal position, but more participants emphasized the associated expenses over the perceived clinical benefits. Very few women appeared to know the benefits of ultrasonography beyond determining fetal position and sex.

Risk perception

There did not appear to be a pervasive or robust understanding of non-cephalic presentation and its associated health risks. Some participants knew that non-cephalic deliveries were dangerous, and the acuteness of that risk perception ranged widely. A mother-in-law related, "[The woman's] confidence broke down when she heard that the baby was upside down. She would not have become so nervous if the baby was normal." (mother-in-law of woman, age 22). Another mother-in-law also relayed a similar sense of

concern and panic when the fetus came out feet first, stating that she prayed and promised offerings to gods and goddesses for the health and survival of the baby, or if not, at least of the daughter-in-law. In both the IDIs and FGDs, some women expressed concern about the possibility of a non-cephalic fetus getting stuck, and that the mother and/or child could die in the process. A majority of women in one older women's focus group stressed how dangerous non-cephalic births are and also how unpredictable they are in terms of survival of the mother or the child. Yet they all agreed that the delivery can be done at home, until the labor becomes so complicated that it cannot be done at home. These concerns were not unanimously held. Also, some women in the focus groups stated that they would not know how to answer some of the questions posed by our facilitator when they have never experienced a non-cephalic birth before, and deferred to participants who had a previous non-cephalic birth.

Some interviewees had never heard anything pertaining to non-cephalic presentation prior to this delivery. One mother-in-law indicated, "Till this day, I hadn't heard of an upside down baby, nor had I seen or heard anything about it. I don't know how it happened." She subsequently noted that she would have taken her daughter-in-law to a facility had she known that the baby was upside down. One woman indicated that the family was simply taken by surprise; "When we saw that the legs of the baby were coming out first, we were kind of shocked and could not think of how the baby was going to be born." In another scenario, a sister-in-law reported confusion about what should be done; a traditional health worker indicated that a breech fetus can be delivered at home, while neighbors said the opposite and implored the family to take the woman to a facility.

It appeared that in many cases, it was not until birth attendants or family members sensed that the labor was prolonged that they chose to seek care outside the home, and not necessarily at the initial point when they recognized that the fetus was breech. Even among those who had minimal exposure to the concept of non-cephalic presentation, many stated that they would have sought care if they had known before delivery.

Fetal malpresentation did not appear to be a systematic part of risk communication during antenatal or intrapartum care. One woman noted, "I know the pain of losing a child; however I never knew about breech delivery. If I had known that my baby was not in the normal position I would have done something. The doctors didn't even tell me once or gave any hints about it." A few women even lacked knowledge on which way a fetus is supposed to present in a normal case; one noted that she did not know that the baby is supposed to present head first until she delivered her first baby. With that said, even those who did receive the risk communication did not necessarily seek intrapartum care. Following an ultrasound diagnosis of a fetus in transverse lie (fetus lying horizontal to the mother), a certified doctor instructed one mother to arrive ten days before the delivery date to be admitted, but she insisted on a home delivery and continued to do so during the intrapartum period despite her family members' insistence on heading to a facility.

Risk perception was strongest among families who had a previous complicated non-cephalic delivery. Those with previous negative experiences (either the woman herself or her family members) sought care and there was a pervasive sense of fear in their rhetoric and behavior. One spent a significant amount of money on a traditional

healer to “prevent the umbilical cord from coming out first again,” while others sought facility care immediately upon discovering at the start of labor that the fetus was in non-cephalic position. Similarly, participants who had heard of negative consequences of non-cephalic births from neighbors or from other sources generally sought care. One participant in an FGD said, “Everyone in my family got scared seeing the breech delivery. One of the people in our village also had a breech delivery and her child died. My family members were very concerned so they kept calling the doctors.” Those who had a complicated home delivery during the pregnancy in question indicated that they would deliver at a facility the subsequent time. In contrast, a few women in both IDIs and FGDs who had a previous non-cephalic delivery but had no complications did not relay a strong sense of concern regarding non-cephalic deliveries.

While perceived risk appeared to motivate care-seeking in many cases, it rarely was sufficient to overcome the barriers to care-seeking beyond the first point-of-contact facility. Several lower-level government facilities in the study area have a policy of immediately referring non-cephalic cases to tertiary facilities, although the protocol is not standardized (Chapter 3). In the handful of situations where women were referred by those facilities to higher care, families asked to try handling the birth there rather than completing the referral. In a few situations, the families were asked to sign what appeared to be a liability form and permission from the guardian before the facility proceeded to care for the woman. Another woman who was referred to a tertiary facility complained, “They [the primary health facility] just said that they couldn’t do the delivery in the facility without giving any concrete reasons.”

Some participants also chose not to receive recommended care after arriving at a facility. Two mothers-in-law reported asking clinicians to avoid C-sections, one because of concerns about a difficult recovery (as the mother-in-law herself had experienced a C-section) and one because she feared that the baby might be swapped by health workers, a boy for a girl, without a family member presiding over the delivery.

Cause of and treatment for non-cephalic presentation

The most common cause of non-cephalic presentation described by participants in both the IDIs and the FGDs was the manner in which a woman sleeps. Several individuals indicated that rolling over while lying down, without getting up first to turn over, causes the fetus to turn. A few others indicated that sleeping on one's back or on the side will cause the fetus to turn upside down. Several indicated that they heard this from doctors, though it was unclear what level health worker they were describing. While this cause was often mentioned, many respondents needed probing before bringing up this information, suggesting that the topic of either non-cephalic presentation and/or its cause was not particularly salient. Some seemed to only indicate that they had heard of this before, but not necessarily that they believed it. Furthermore, several participants in the younger women focus groups indicated that these beliefs were just held by older generations. Other participants indicated that the position of a fetus is simply god's will, and this theme of "mercy of god" and "fate" recurred in the older women focus groups.

Many individuals described medication that can be taken to straighten the baby. One woman reported taking up to seven medications. The younger women's focus groups

also described such medication, but qualified it by claiming that even with the medication, there is no guarantee that the fetus will rotate. In the older women's focus groups, some participants raised the ability of local health attendants to both detect and to rotate a non-cephalic fetus in the womb, while the role of a local health attendant was not emphasized in the younger women's focus groups. One mother-in-law who was a traditional birth attendant indicated that she is able to tell the fetal position through abdominal palpation and that she is also able to rotate the fetus, something that is recommended clinically only if there is a trained professional who can also monitor the fetus using ultrasonography.

Fetal / neonatal death

Just under half of the households interviewed experienced a stillbirth or a neonatal death. We do not expect that all of these deaths were caused by complications associated with non-cephalic presentation. Some women strongly associated the cause of stillbirth / neonatal death with the fetus having gotten stuck in the process of delivery. One simply said, "The baby got stuck, it flailed about two times and then died. The baby died because it got stuck." One family strongly blamed the health care workers and their handling of the delivery, having pushed and pulled on the fetus multiple times. Others showed a fatalistic or religious understanding of the death. One woman noted, "this baby was born after (a previous infant who had died). That was why this baby also died. That is known to god only." One mother described her concerns and fear when she saw "about half of the baby hanging out" of her daughter, but then added, "Luckily I had not done any harm to anybody, so god also did not do any harm to me and the baby was born."

Many families, both in the context of fetal malpresentation and in the context of fetal / neonatal death, had conflicting relationships with fatalism / religiosity and trust in the health care system. While they indicated that only god knows what will happen, they also made comments on how they did or would have sought facility-level care or sought medication to deal with the dangers of fetal malpresentation. One woman in a focus group described the conventional intrapartum care-seeking process as first attempting to deliver at home, then going to a local doctor if problems arise, then going to a hospital if further problems arise. Yet, she proceeded to add, "All depends on the fate of the patient. If she is lucky, she is saved, and if not, then she dies." A few women did not seek facility care because of this conflict between their beliefs and health care; some believed that the interventionist actions of facilities would interfere with god's timing and will.

Some described the pain the stillbirth/neonatal death has brought upon the family. One mother-in-law lamented, "When we found out later that the baby had died, we felt like falling off a tall building..." In addition to facing the loss of a fetus/neonate, some families also described the fear of the woman dying from complications during delivery. One woman, upon realizing that her fetus was in non-cephalic position, expressed concerns out of fear for her high-risk pregnancy; "I started crying and shouting because I have four children and if anything happened to me my children would be helpless. I don't have either a mother-in-law or a sister-in-law. Who would take care of these four children?"

Discussion

Non-cephalic presentation has a prevalence of 2-3%, making it a relatively rare condition compared to other pregnancy-related health issues such as anemia, pre-eclampsia/eclampsia, and malnutrition, but its acute risk for adverse outcomes is much higher. We observed inconsistent risk perception toward and care-seeking for this condition in our study community. As Lee et al. suggest, early prenatal identification and management of low prevalence but high-risk complications may be one approach to address intrapartum complications.[11] Several other studies have shown high positive predictive values for low-prevalence risk factors.[9,10,12] Implementation of such strategy must consider the existing burden of antenatal care communication on both the health system and the families receiving such communication. This concern was highlighted in an evaluation of a community-based maternal and neonatal care promotion program in Nepal, as some stakeholders reported concerns about certain antenatal care messages getting "lost" because of the quantity of messages provided to families.[13] Other programs and studies in developing countries have also reported on the minimal amount of time health care providers currently spend on health counseling,[14,15] raising issues of competing priorities, quality of care, and human resource burdens.

Only two women in our study were aware that their fetus was in non-cephalic position prior to the beginning of labor, an unsurprising finding in an area with limited ultrasound access. Ultrasonography is the only gold standard method of detecting non-cephalic presentation prior to delivery, and access and/or utilization are sparse in low-resource settings. In our study area, only about a quarter of women received an obstetric

ultrasound exam during their most recent pregnancy (Chapter 4). It is often too late to address issues by the time clinical issues appear in the intrapartum period because of the potential for acute insult to the fetus. This makes access to ultrasonography particularly important. Several studies have reported on the introduction of ultrasonography into low-resource settings using lower-level health cadres,[16-18] and ultrasound is becoming more affordable and portable.[19] This may help increase access, even in rural, low-resource areas. Further research should examine whether antenatal screening for risk factors like non-cephalic presentation would impact care-seeking behavior and ultimately reduce adverse birth outcomes.

Identification of a risk factor and perceiving its severity are only the first steps toward seeking and receiving appropriate care. Much has been written on the barriers to maternal care-seeking, often using the framework of the three delays model: the delay in the decision to seek care, the delay in reaching the facility, and the delay in receiving appropriate care.[20] Factors relevant to these delays, like cost, transport, distance, and permission from a household decision-maker, were mentioned in our interviews. Birth preparedness may alleviate some of these concerns; for instance, a study in Nepal reported that birth preparedness (e.g. saving money, arranging for transport, finding a blood donor) increased the odds of a facility-based delivery.[21] Yet, there may be barriers to address even to inspire birth preparedness; for instance, Matthews et al. reported that in southern India, planning for obstetric emergencies was considered prophetic, and thus discouraged.[22] We also identified other barriers that are not highlighted by the three delays model, such as refusal to accept the care that is given at the facility. A study from

Tanzania indicated that women associated facility births with severity, and many feared having to undergo C-section if they attended a facility.[23] An Indian study also reported similar findings.[24] It is also important to consider the practical implications of referrals to facilities; while important to seek care at a facility, families often find themselves in a race against time. It is unclear in such situations whether they are better off at home or at a lower-level birthing center than attempting to reach a tertiary facility that is located hours away.

Poor care at a facility was not a salient theme in our interviews, but one of our interviewees vividly described mistreatment at a facility. That household strongly attributed the infant's death to poor clinical management. Existing literature has highlighted facility mismanagement related to non-cephalic presentation. A report by United Nations Population Fund and EngenderHealth described observations from Chad that if the traditional birth attendant during delivery cannot feel the head of the baby due to poor positioning, she will hold the woman by the ankles and shake her in the hopes that the fetus will rotate, a behavior that could potentially lead to prolonged labor and obstetric fistula.[25] Several other studies have highlighted improper or inconsistent management of breech deliveries[24,26,27] and we also witnessed inconsistent protocol among the facilities in our study area (Chapter 3). Non-cephalic deliveries should be conducted in Comprehensive Emergency Obstetric Care facility, so C-section capacity is available if needed. Bhutta et al. reported that planned C-section for term breech presentation has supporting evidence of reducing stillbirths in low-resource settings, and

also highlighted the potential for task shifting in areas where doctors are not readily available to perform the surgery.[28]

Related to mismanagement, another pervasive theme was the use of injections during labor and delivery. Injections appeared to be used to aid or quicken labor and delivery. Clinically, uterotonics can be used to help induce contractions, and should be used while monitoring the fetus; however, participants seemed to describe the use as indiscriminate – not a decision based on clinical need, but standard practice. A literature review has highlighted this issue, with use of uterotonics ranging widely from 1-69% during home births in low- and middle- income countries.[29] Such haphazard use of uterotonics could lead to negative health consequences, which has been previously observed in our study area.[30] Improper usage has been reported elsewhere as well.[31,32] Other qualitative studies have highlighted how women associate uterotonics with positive effects on the delivery,[29] a perspective shared by many of our interviewees.

Two other key interview themes were cause and treatment of non-cephalic presentation. There are risk factors that may make non-cephalic presentation more likely, such as placenta previa and hydrocephaly. No specific cause exists however, and the only treatment is for trained health personnel to attempt to invert the fetus inside the womb and/or to have proper care at the time of delivery. While women acting on some misunderstandings reported in our study (e.g. altering the way one turns over while sleeping) may not necessarily be harmful to maternal and fetal health per se, such beliefs may give mothers a false sense of security by trusting that the fetus will be in a cephalic presentation or anxiety by thinking their actions may cause the fetus to be in poor

position. Also, it is unclear what medications were actually being prescribed to women to rotate the fetus, and the potential harm of the medication.

A strength of our study is that the prospective data collection of the parent study allowed us to efficiently identify women who experienced this specific event, and also capture the experiences and perceptions from both home and facility deliveries and from those who experienced a fetal/neonatal death and those who did not. The interviews were conducted within a few months of delivery, minimizing recall bias. Also, the research organization through which these interviews were conducted has good rapport with the community, having worked there for over 25 years on issues related to maternal, neonatal, and child health. One weakness of the study is that we did not examine health providers' perspectives on non-cephalic presentation. Also, while our interviewers underwent a rigorous one-month training, they were conducting qualitative research for the first time. Finally, there may have been reactive responses, as our staff were often perceived by many community members as "doctors."

Conclusion

Non-cephalic presentation is a major predictor of adverse pregnancy outcomes, increasing the likelihood of fetal and neonatal mortality and morbidity in low-resource settings. Findings from this qualitative study suggest that there is no consistent or pervasive understanding of the risk of and appropriate care for non-cephalic births in rural Nepal. The study highlights the need for incorporating risk communication regarding this particular condition into antenatal care materials, and the need to educate

the contributors to maternal care, including the women themselves, household decision makers, traditional birth attendants, and facility-level providers. With that said, the health community must attend to the myriad of other barriers to care-seeking beyond identifying a danger sign. It is important to place the value of risk communication in the realistic context of a low-resource setting where women face many other hurdles to seeking and receiving appropriate facility-level care during labor and delivery.

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Chapter 7: Barriers and facilitators to intrapartum care-seeking

Background

Due to complications during labor and delivery, 1.2 million stillbirths and one million first-day deaths occur annually.[1] A large majority of these deaths occur in low- and middle-income countries (LMIC), where access to health facilities is limited. Save the Children's 2014 Ending Newborn Deaths Report estimated that newborn mortality could be reduced by 38% with more equitable distribution of care, and previous literature has noted that both intrapartum-related stillbirths and neonatal deaths can be reduced by over 40% with a skilled birth attendant present during labor and delivery.[1]

In order to address inequities in health access during labor and delivery, Nepal has implemented the Safer Motherhood Program, which among other things includes financial incentives for women to deliver in health facilities.[2] The intrapartum care at government birthing centers is also free of cost. Potentially due to such innovative programming and also improvements in socioeconomic conditions, such as increasing education attainment among women, there has been a drastic shift in the overall facility delivery rate. In the decade between the 2001 and the 2011 Nepal Demographic and Health Surveys, women delivering in a health facility increased from 8.5% to 40.6%.[3] Nevertheless, there is still a large percentage of women who deliver at home, many with no skilled birth attendants present, which exposes the woman and her child to high obstetric risk.

As a part of a study that explored community perceptions of non-cephalic birth, we collected information pertaining to barriers that keep pregnant women in rural Nepal

from seeking and/or receiving intrapartum care at a birthing facility, and also to explore what inspired those who did deliver at a facility to do so. We explored the salient factors that impede facility-based deliveries, even in the context of a conditional cash transfer program to improve formal health care utilization.

Methods

The data for this study were collected as a part of the qualitative study on care-seeking / caregiving behavior on and perceptions of etiologies and consequences associated with non-cephalic presentation. See Chapter 6 for the full description of the methods. Briefly, we identified through the parent study women who had a non-cephalic birth between two and twelve months prior to the interview. For the first eight women, we also identified a female decision-maker of the household to interview simultaneously, but separately, to gain insight on perspectives of both the care receiver and the caregiver. As the two-interview format did not add much additional data, we altered our study design to conduct interviews solely with the primary female decision-maker, or if not available, the woman who gave birth. A total of 34 interviews from 26 households was conducted. To understand the community perspective toward childbirth and non-cephalic presentation, we also conducted two focus groups with younger women (at least two children, with at least one being under five years of age) and with older women (at least one grandchild).

In addition to questions specific to non-cephalic presentation, the interview guides for the in-depth interviews (IDI) included questions regarding their decision behind

where to deliver (at home or at a facility), and the guide for focus group discussions (FGD) included questions on what the respondents perceived as benefits and disadvantages of home and facility deliveries respectively.

Results

We initially interviewed eight pairs of women and their respective decision making family members: six mothers-in-law, one biological sister who was also a sister-in-law by marriage, one grandmother-in-law (family members are labeled by the relationship to the woman who delivered the baby). We then interviewed one interviewee per household: six women, six mothers, five mothers-in-law, and one sister-in-law. A total of 26 households were represented in 34 interviews. The two focus groups of younger women had eight participants each, while one older women's focus group had eight participants and the other seven.

Care-seeking specific to non-cephalic presentation

A large majority of women were unaware prior to the start of labor that the fetus was in non-cephalic position. There was no consistent risk perception of non-cephalic presentation among the respondents. Those who had a previous bad experience with a non-cephalic birth appeared to seek care immediately upon discovery that this fetus was non-cephalic as well. Care-seeking behavior did not appear to change for others; it was often not until the labor was prolonged that the families sensed a need for outside care.

Some interviewees did state that they would have sought care if they had known earlier about the position of the baby. More details are available in Chapter 6.

Financial cost

The most salient theme pertaining to barriers to receiving facility-based intrapartum care was financial costs. Despite the conditional cash transfer system that awards 500 Nepali rupees (approximately 5 USD, as of October 2015) to women delivering at a facility, and the cost of facility-based intrapartum care itself being free at birthing centers,[2] many women mentioned how poor individuals still cannot afford to seek care. A mother-in-law stated, "You (referring to the study staff) are people with money but we are poor. If you had even the slightest pain in the abdomen when you are pregnant, you would have gone to the hospital immediately but we are poor. It costs money to go to the hospital for delivery. It is necessary to take a loan from others." Several mentioned the costs associated with transport, but also the difficulty in finding transport promptly. For instance, one woman stated, "No one agrees to go regardless of how much a poor person pleads, but they are ready to go even if a wealthy person only asks once." Many participants were also unfamiliar with the conditional cash transfer system. Although some appeared to have heard of or know of the cash transfer program, none of the interviewees reported the cash as a motivator to seek care. Only one participant in a focus group mentioned it as a benefit of delivering at a facility.

Others mentioned hidden costs to care-seeking. For instance, one stated that "even in the government hospital, they won't write the name (on a sign-in sheet for patients)

unless we give him some money." Another woman mentioned nonchalantly that she happily provided "thank you" money to the staff when her grandson was safely born, but that she had to plead out of giving more. One household claimed that they were not able to promptly seek care, as the elder brother of the husband would not agree to provide financial support for the couple to seek care. In one of the maternal focus groups, they also mentioned that guardians just wait for the delivery to take place at home with little care for the health of the mother and the baby, out of concern for cost. Several interviewees also expressed their disappointment and anger that a fetal or neonatal death occurred despite investing a large sum of money toward facility-based care.

Poor perception of health facilities and providers

Descriptions of poor treatment by health providers at a facility also arose from both the interviews and focus groups. One focus group, comprised of older women, had a heated discussion with conflicting opinions pertaining to the treatment of women by facility-based providers. Some reported that nurses physically beat the women; one woman said that her daughter-in-law was beaten so badly that her cheeks were swollen. Others stated that such physical abuse does not occur, and others qualified the beating as only happening when the women cry too much, putting the onus on the patients rather than the providers. The focus group of younger women also mentioned that the facility does not let women cry, and does not allow family members to be near the patient. One participant mentioned that a woman gets her hands and feet tied up, but another interrupted that that only happens to mothers who "make trouble." In IDIs, a woman

stated that facility providers would tie the pregnant women's hands and legs down with a chain and another woman said that they beat you if you scream. Both of these comments were not personal experiences, but hearsay. Several others also mentioned that while they can deliver a child with a lot of support from family and neighbors at home, they would not get any emotional support if they were to go to a facility. Also, while not as malicious and explicit as the beatings and poor treatment described above, several women described negative experiences during the delivery process. One woman said, "I told the doctors that I cannot do it, as I was already weak. I told the doctors to give me an injection. The doctors didn't listen. I told them that I couldn't give birth but the doctors and the nurses kept hitting my thighs. Both my thighs were swollen."

Other facility-related barriers were mentioned as well. Several women stated that it was embarrassing to have male doctors look at them, and did not want a male doctor inserting his hands into their vaginas. Others had an impression that facilities are very interventionist, and feared that they would resort to surgery quickly. Some also described medical intervention as interfering with god's will and timing.

There was also a theme of distrust in the intentions of the health staff. One stated that "nurses and doctors don't care whether the mother dies or lives until it's time for the baby to be delivered." Another interviewee expressed strong suspicion that her grandchild was being kept in an incubator for the facility to make more money from her family, and in response to this suspicion, other individuals also seeking care at the same facility told her to keep quiet or the doctors might do something to the baby. She stated that she stayed quiet out of fear for her grandchild's well-being.

Permission to seek / receive care

Several women spoke about needing to seek permission for care, either to leave home for a facility or once arriving at the facility. One woman noted that while she desired to seek antenatal care, her mother-in-law scolded her and her sister-in-law, declaring that when she was their age, nothing was given to her, and questioned why they would need to seek facility-level care. In another instance, despite the circumstances being urgent in relation to the pregnant woman's health, a mother-in-law needed to find her own husband (the father-in-law of the pregnant woman) for permission to seek further care. Even after arriving at the facility, several interviewees mentioned that facilities sought signed permission from the guardian of the woman, which is usually her husband or another male member of the household. It was unclear from the interviews whether this permission was for any care at the facility or for urgent cases, and whether it was for liability purposes. In one scenario, a doctor indicated that he would only provide care if a guardian signs a "paper." The mother-in-law described the scenario once arriving at the facility, "I was weeping and said please take my thumb mark as the guardian of my daughter-in-law, I am her mother-in-law. The doctor did not agree. She said that the husband of the pregnant woman must sign." In another circumstance, a family member asked the facility to proceed with providing care, despite having been referred to a tertiary institution because of the woman's high risk.

Role of a facility

Most interviewees viewed seeking facility care as something only for urgent circumstances. A recurring theme was the need to go to a facility to save the life of the mother or the child, and that care was not sought until decision makers perceived acute risk. One participant in a focus group mentioned, with others agreeing, that children are born faster at a facility because of injections and medicines provided there. Another woman highlighted that one benefit of a facility delivery is that further referral is facilitated as necessary. It appeared that a very strong facilitator for care-seeking was simply that a woman had had a prior negative home birth experience, and thus desired to deliver a child at a facility for the subsequent birth. When women were asked about the benefits of facility-based care, many listed the receipt of material benefits such as money (from the government-sponsored conditional cash transfer system), baby cloth, and medicine, but often only after probing.

Concept of care

Some women reported that the doctors "don't say anything" to them during an antenatal care visit and one also reported that they received something written on a piece of paper from the doctor, but that they did not comprehend what was on it, as they were illiterate. The concept of a health care provider was fluid, in that there was minimal linguistic differentiation made among the various individuals in the community who serve formal or informal health care roles. While there are specific traditional roles, like traditional healers (*dhami jankri*) or traditional birth attendants (*hatkini*), who had distinct

names and responsibilities and were clearly distinguishable by the interviewees, the interviewees also very freely used the English word “doctor” to identify health care workers, encompassing certified MBBS doctors in government or private facilities, certified health workers who are not MBBS doctors, individuals found at the local marketplace who do not fit under the roles mentioned above, and also our own study staff who do not have clinical training. Across several interviews and focus groups, respondents asked our interviewers questions regarding non-cephalic presentation, assuming they would know more as “doctors.”

Postnatal care

There appeared to be no urgency for immediate postnatal care as long as the infant was delivered and breathing. Several interviewees described home-delivery situations where the newborn appeared to suffer from asphyxia, but there was no urgency to seek subsequent care at a facility after the infant started breathing. As an example, one woman who was on her way to a facility on an ox cart delivered en route. The infant appeared to be asphyxiated, and the mother-in-law made resuscitation efforts for a self-reported one hour. Once the infant started breathing, the family simply returned home rather than continuing on to seek immediate postnatal care for the infant and the woman. The mother-in-law insisted that the infant was “alright,” despite she herself having described that the infant “was dead” and that she had no hope for its survival before it was revived. A neonate who reportedly did not breathe for two hours and another who did not breathe for half an hour following home deliveries did not receive further care

once family members or traditional birth attendants managed to get the baby to breathe, and one other baby was only referred to a tertiary facility a full day after delivery, despite it being born weak and of very low weight.

Traditional beliefs

Many individuals mentioned traditional beliefs pertaining to pregnancy, but more often than not, it appeared that those traditional beliefs did not necessarily conflict with care-seeking. While the concept of fate and god's will were mentioned several times in interviews, the same individuals described the care they sought or would have sought. In the grandmothers' focus group, it was also mentioned that seeking care at the facility and having an operation implies that a woman must have sinned. It is unclear to what extent these traditional beliefs impede proper care-seeking.

Discussion

Our study highlighted barriers and facilitators of seeking facility-level intrapartum care, both specifically among households that recently experienced a non-cephalic birth and more generally among mothers and grandmothers in the community. The associated financial costs appeared as the most salient barrier mentioned throughout the interviews and focus groups. Cost as a major barrier has been highlighted in many previous studies.[4,5] In our context, however, cost was perceived as a barrier despite the facility-based intrapartum care itself being free and the availability of a cash incentive for delivering at a facility. The other costs involved, such as transport and the hidden costs of

paying off health providers, still appear to be a large hurdle for families in this community. About a fifth of the population in Sarlahi District has no cash sources of income,[6] which suggests that the initial financial barrier would still be too high to get to the facility to take advantage of the cash transfer system. The inequitable distribution of the benefit of the program was highlighted in a study from nearby Makwanpur District; they found that the cash transfer program in the first two years of implementation benefited wealthier families disproportionately.[7] The Lancet Maternal Survival Series underlined the burden of out-of-pocket costs often associated with maternal care in LMICs, and made a case for removal of user fees and for universal coverage for pregnant women.[8] Yet, our findings highlight that covering the direct cost of care is often not enough. Another study conducted in Pakistan that examined barriers to neonatal care-seeking from a primary to a tertiary care facility made a similar observation; despite medical care being free and transport to a referral hospital provided by the study, a little over 50% of all families whose newborns were referred stated financial difficulties as a reason behind refusing referral.[9] A study in Bangladesh similarly reported newborn referral completion rate of a little over 50%, even with free care and transport.[10]

A landscape review conducted on respectful care highlighted seven types of disrespect and abuse women and their family members incur at facilities: physical abuse, non-consented care, non-confidential care, non-dignified care, discrimination, abandonment of care, and detention in facilities.[11] The experiences raised in our interviews and focus groups mainly fit the physical abuse and non-dignified care categories. The authors of the landscape analysis highlight many potential contributors to

such an environment, at the individual/community level (e.g. normalization of disrespect and abuse, lack of community engagement and oversight), national level (laws and policies, governance and leadership), and facility level (lack of standards and accountability, provider prejudice). Also contained in the facility-level category is the burden on a health provider due to weak health systems and personnel shortages. For example, a study conducted at a district hospital in Malawi showed great burnout rates among maternal health staff, with nearly three-quarters of the staff reporting emotional exhaustion, and concluded that burnout rates were higher among maternal health staff compared to other health workers.[12] We did not have the opportunity to interview providers as a part of this study. It is important to understand the contextual contributors to poor facility care, and understand whether health providers have the right resources to provide appropriate and respectful care.

For intrapartum care, the interviewees saw minimal preventive value in attending a facility. A study conducted in Maharashtra, India, noted that low socioeconomic status did not impede maternal care-seeking if women perceived the benefits of care to outweigh the financial cost. It also noted that women did not use services, even when available, if they did not perceive benefit.[13] It would be invaluable to make promoted antenatal, intrapartum, and postnatal health care more relevant to the public in order to increase demand and perceived value.

Many women in this community are still severely restricted in their ability to seek care. No woman had the agency to seek and receive care on her own, whether such constraint came at the household or facility level. Previous research on involving husband

during antenatal counseling has been positive. A randomized study at a major facility in Kathmandu showed that male involvement during antenatal visits increased the likelihood of a woman receiving a postnatal check-up and also of making birth preparations.[14] The study also reported that providers felt positively about couples-friendly maternal health services, and that husband involvement would improve the quality of care.[15] We must continue efforts to improve female status through promotion of education and providing opportunities for economic independence. In the meantime, exploring ways to provide more knowledge and increase risk perception among the traditional decision-makers, in the form of husbands or mothers-in-law, may bridge the gap until women have the agency to make care-seeking decisions on their own.

A strength of this study is that it collected in-depth qualitative data pertaining to care-seeking decisions. Much of the existing literature on maternal care-seeking quantifies the barriers and facilitators into predefined categories, and fails to capture how barriers may interact and compound. By conducting interviews with recently-delivered women and their household members, we were able to capture a more nuanced understanding of decision making pertaining to intrapartum care. The household members interviewed in this study were selected from among those who recently experienced a non-cephalic birth. While the findings that were explicitly linked to the experience of having a non-cephalic birth were reported as such in Chapter 6 and in this chapter, other findings may also be more strongly relevant, if not only relevant, to those who experienced a non-cephalic birth.

Conclusion

Despite improvements in the facility delivery rate in Nepal, a majority of women still experience childbirth at home under unsafe conditions. Programs like the conditional cash transfer system to award those who deliver at a facility have made an attempt to lower the hurdles that lie between many women and care-seeking. Our study highlights the remaining household- and facility-level barriers to care-seeking that need to be addressed to provide safer, more equitable care to pregnant women in low-resource settings.

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Chapter 8: Discussion

Summary of major findings

Globally, 2.7 million neonatal deaths[1] and 2.6 million stillbirths[2] occur each year. About a quarter of neonatal deaths[1] and half of the stillbirths[3] are attributable to intrapartum-related causes. The incidence of adverse intrapartum-related outcomes is also high in our study area, located in the southern plains of Nepal; our study population has a fresh stillbirth rate of 18 per 1000 births, early neonatal mortality rate of 17 per 1000 live births, and a neonatal encephalopathy rate of 5.0%. Focusing on two fetal characteristics that are detectable antenatally, non-cephalic position and multiple gestation, we noted significantly higher rates of adverse intrapartum-related outcomes among these births. Non-cephalic births had a five-fold (aRR 4.87, 95% CI: 3.74-6.34) increase of experiencing a fresh stillbirth, early neonatal mortality, or neonatal encephalopathy, compared to cephalic births. Examining fresh stillbirths alone, the risk was 13-fold higher (aRR 12.69, 95% CI: 7.96-20.21). 21% of fresh stillbirths was associated with non-cephalic presentation. Twins had a three-fold increase (aRR 2.97, 95% CI: 2.06, 4.28) of experiencing a fresh stillbirth, early neonatal mortality, or neonatal encephalopathy. Examining early neonatal mortality alone, the risk was six-fold higher (aRR 5.91, 95% CI: 3.54, 9.85). 5% of early neonatal mortality was attributable to multiple gestation.

Among women who experienced a non-cephalic or multiple birth, only 25% and 36% were aware beforehand respectively. This low percentage is unsurprising in light of our findings regarding the utilization of obstetric ultrasonography in the study area. 64% of women reported having heard of ultrasound (or video x-ray, a more commonly used

term in the community) and 27% of women had received an obstetric ultrasound exam in their most recent pregnancy. Receipt of an ultrasound exam was more common among those with higher socioeconomic status. Also, 7% of women who received an exam reported fetal sex determination as the purpose, and we also noted that mothers with no live born sons but three or more live born daughters had a higher likelihood of receiving an exam.

Early diagnosis of these conditions may allow for birth preparation, and subsequently better health outcomes. Taking this and the low access to sonography into consideration, we assessed how validly lower-level health workers can diagnose intrapartum-related risk factors, using a portable ultrasound machine in a home-based setting. Auxiliary nurse midwives (ANM) were tasked to diagnose non-cephalic position, multiple gestation, and placenta previa among pregnant women in their mid- to late-third trimester. Despite only receiving two weeks of training, we observed high validity against the gold standard readings. Furthermore, we also observed trends toward improved health outcomes among those who received sonography and had either a non-cephalic or multiple birth. We reported that women who were diagnosed by our ANMs as having one of the aforementioned risk factors had higher rates of delivering at a facility and lower rates of adverse outcomes (fresh stillbirth, early neonatal mortality, neonatal encephalopathy). These results however are inconclusive due to small sample size and a non-randomized comparison group.

To better understand what a diagnosis of non-cephalic position would mean to women in this community, we conducted in-depth interviews with women who recently

had a non-cephalic birth and focus groups with younger and older women in our community. Perceived risk toward non-cephalic birth varied widely. Those who had a previous non-cephalic birth had the strongest perception of risk, many having had a negative prior experience. On the other hand, there were other women who did not show any understanding of risk pertaining to non-cephalic birth. Very few women were aware of their condition prior to delivery, and a few women also expressed confusion by the implication that one can diagnose fetal position prior to delivery. There were false understandings of cause and treatment for non-cephalic position. Several women reported that the position a mother sleeps in influences fetal position. Some women had either heard of or had taken medication to reposition the baby, with some reporting such medication being recommended by a clinician.

Discussion

While the field of public health generally tends to target highly prevalent risk factors, we explored the potential health impact of targeting low-prevalence risk factors with very high risk. The prevalence of non-cephalic and multiple birth were just ~2% respectively in our study area, but the adverse outcome rates among those births were approximately 40% and 30% respectively. This implies that these risk factors are good predictors of adverse outcomes. Also, even if these risk factors do not necessarily lead to an intrapartum-related complication, they may still serve as a signal for other complications. For instance, both non-cephalic and multiple births are more likely to be preterm; the preterm rate was 16% among cephalic births and 24% among non-cephalic

births, and 15% among singletons and 49% among twins in our study. Preterm birth is the leading cause of neonatal death, taking up 36% of the causal pie, and the unintended benefit of capturing non-cephalic and multiple births may be that preterm births will receive better immediate postnatal care. So even if the causal mechanism is not operating through intrapartum-related complications, these mother-newborn dyads may benefit from the antenatal screening.

Our experience with the ANM ultrasound validation component of the thesis represents some of the difficulties of introducing complex technology to low-resource settings. The numerous breakdowns of the machine required technical assistance from the manufacturer's office in the U.S., and for our purposes, the fast turnaround of replacing broken machines only occurred because of the frequency of study researchers traveling between the U.S. and Nepal. Transport on motorcycles on bumpy roads, with the ultrasound probe packed in a bag provided by the manufacturer, led to damage of the probe, which again had to be replaced through the U.S. manufacturer. We subsequently created a padded case and had a local carpenter create a probe and gel stand for use during exams. We also operated under conditions where the parent study was conducting active pregnancy surveillance, which then allowed for the automated production of a list of pregnant women in a certain range of gestational age on a certain week. Such diligent surveillance is impractical in programmatic settings. These conditions create skepticism toward scaling up home-based visits.

Keeping those issues in mind, there is potential for introduction of obstetric sonography through other mechanisms. For instance, there may still be potential for home

visits with the use of more portable technology. There are mobile-based devices, like General Electric's Vscan, the development of which was largely funded by the National Institutes of Health.[4] We consciously avoided a mobile-based device for this study, as we did not want the ANMs' diagnostic accuracy be dependent on external factors like the visibility of a small screen. However, with confidence in their skillset, it may be feasible to utilize a much more portable piece of equipment. The robustness of such equipment in low-resource settings will need to be tested prior to scale-up. Also, having shown the high validity at which lower-level health workers can diagnose these conditions, there is great potential for facility-based task shifting in a country with very limited availability of certified radiologists. The Kathmandu Post, an English-language Nepal newspaper, reported in 2013 that the Nepali government has been considering training nurses to operate ultrasound machines to more remote, lower-level facilities. Our collaborator Dr. Ram Kumar Ghimire was interviewed for the article (prior to involvement in this study), and he expressed his concerns toward allowing exams to be conducted by individuals new to the field, and emphasized, "There must be a defined framework of the task."[5] All of these considerations need to be taken to heart in evaluating the extent to which task shifting would be successful. Facility-based sonography can include antenatal screening, but also screening at the time of labor for immediate referral to tertiary facilities. The availability of sonography at primary health centers may also inspire women to make antenatal care visits. While anecdotal, clinicians involved in another sonography program in the mountainous district of Humla were quoted by a Nepali newspaper, "Most of the women trust us more these days. Some of them may look confused but they feel assured"

and also that "when we worked solely with our hands, there were times when we could not come up with an early diagnosis, and things would go wrong, and that tarnished their trust in us."[6] Availing health workers of this technology may improve relations between the community and facilities.

Training lower-level health workers to use sonography to its full diagnostic capacity would be difficult, considering the complexity of radiology and the vast number of diagnoses that can be made in obstetrics and in other specialties. However, training them to diagnose a small set of easily diagnosable risk factors may be better than the continued proliferation of unregulated private ultrasound clinics. We noted during our interactions with facility staff in our facility survey that there are private clinics that are notorious for providing poor quality images. One facility staff member indicated that they had received a sonographic image of another organ from the private clinic run by an MBBS doctor instead of an image of a uterus. The same doctor was a physician at a local birthing center, and it appeared that he was referring the patients from this public, no-fee birthing center to his for-fee private ultrasound clinic. The Kathmandu Post in 2014 also reported on doctors at Bheri Zonal Hospital who were pocketing 30-50% commission from private clinics for referring patients for blood tests and ultrasound exams.[7] While these are only anecdotes, there are existing concerns regarding the quality of exams being conducted by non-radiologist clinicians under these unregulated circumstances, and concerns related to private ultrasound clinics, such as the conflicts of interest demonstrated in these examples or access to illegal fetal sex determination.

In the qualitative study, we noted several points of inaccurate clinical information pertaining to non-cephalic presentation. For instance, several women reported either having heard of or taken oral medication to reposition the fetus. Disturbingly, such medication was being prescribed by clinicians in some cases. It is unclear from our study what was actually being prescribed, and whether such medication would have been harmful for the fetus or the mother. During the ultrasound visits, we also encountered one woman who had presented to the ANMs a birth control pill that would prevent her from getting pregnant forever. These scenarios are most likely only the tip of the iceberg of improper medication prescription, whether from clinicians or from local pharmacies. It is unclear to what extent these issues could cause adverse health outcomes.

Study limitations

There are several limitations to the dissertation research. For the gold standard assessment of the ultrasound diagnosis, the truest "gold standard" would have been to have a trained sonographer conduct an in-person exam immediately after the ANM, but we were unable to recruit a certified sonographer for an extended period of time to participate. We tried to address this issue by implementing a systematic protocol for labeling the still images. The labels provided sufficient information for the gold standard reader to determine the direction of the probe and where the probe was placed on the mother's stomach. However, we acknowledge that there remains a possibility that the diagnosis made by a gold standard reader through the still images is not the true diagnosis. This issue applies mainly to the placenta previa diagnosis; the placental edge is harder to

detect later in pregnancy, with the fetal body blocking the view. Hence, a gold standard diagnosis would be even more difficult through still images.

The main aim of the ultrasound study was to determine whether lower-level health workers can accurately detect obstetric risk factors. The study was not powered to detect differences in facility delivery rates or in health outcomes between those who received an ultrasound exam from our study staff versus those who did not. It was also not a randomized controlled trial. Thus, the results we reported comparing those enrolled and not enrolled in the ultrasound study should be interpreted with caution because the background factors that differ between the two groups may bias the outcomes.

Several key indicators we used in our study relied on maternal self-report. For instance, fetal presentation was a self-reported indicator that would likely have been hearsay from birth attendants, rather than the mother observing the presentation herself during delivery. With that said, other family members, like the mother-in-law, are often present at the data collection interviews, thus likely to interject if inaccurate responses are given by the mother. Also, according to a validation study of women's self-report conducted in Mozambique, women were able to recall presentation with high accuracy.[8] Also, we calculated gestational age using the date of last menstrual period to determine who was eligible in the sonography study. Pregnancy surveillance is conducted every five weeks, so the recall of date of last menstrual period would be no more than five weeks, except if women were amenorrheic. We may have captured some women earlier than 32 weeks gestation; earlier gestation pregnancies may be easier for diagnosing all three of the risk factors because of the smaller fetal size.

Recommendations for future research

Our study provided evidence that lower-level health workers can use ultrasonography to diagnose basic obstetric risk factors with high accuracy. There was also a hint that the rate of adverse outcomes may be lower among those who experienced a non-cephalic or multiple birth and had received an obstetric ultrasound exam. In order to strengthen the evidence of the impact on health outcomes, a randomized trial providing an obstetric ultrasound exam should be conducted. One study design may be to conduct an implementation research study, randomizing birthing centers to availability of obstetric sonography. We can determine if adverse health outcomes are less prevalent among those who received an exam and specifically among those who were diagnosed with a risk factor, and also compare facility delivery and birth preparedness rates. We would expect some contamination in this study, in that women residing closer to control facilities may come to intervention facilities for care upon hearing about the availability of sonography. This would be an interesting question in itself, to determine how desired a commodity obstetric ultrasound is for families in this community, and the volume of births could be compared pre- and post-intervention. Intention-to-treat and per-protocol analyses would be required to determine the extent to which contamination impacts the results. Also, another question is whether women not being diagnosed with a risk factor through an ultrasound exam deters women or households from seeking facility-based care. We did not witness lower facility delivery rates in our study among those who were not diagnosed with a risk factor, but we did not disaggregate the data as to whether there was

an intention to deliver at a facility prior to the exam and whether women changed their minds specifically because of a "good" diagnosis following the exam.

In our study, we only explored ultrasound risk screening in late pregnancy as a potential task for lower-level health workers. There are other potential diagnostic tasks, such as gestational age dating, congenital abnormality detection, and also diagnosis of childhood and adult diseases. Particularly with gestational age, accurate dating may allow us to better address another major killer of neonates: preterm birth. There are effective interventions such as postnatal thermal care that could effectively reduce adverse outcomes among preterm births, but a major barrier to intervention is not knowing the accurate gestational age. It is unclear how much motivation an early diagnosis adds to either a pregnant woman or a household decision maker in contexts where there are major cultural, social, and/or economic barriers to seeking antenatal or intrapartum care.

We only mention sonography above, but there is a need for further exploration of other means of antenatal risk screening. Non-clinical risk factors such as maternal height and weight (and calculated BMI), waist width, gravidity, and age can be captured without much technology or clinical expertise. While a single one of these factors is not expected to be predictive enough of adverse outcomes, some interactions of these risk factors may have better predictive values of adverse outcomes. There have also been promising new diagnostic technologies being introduced in the field of maternal and neonatal health in low-resource settings. Much innovation is being led by the Johns Hopkins Center for Bioengeering Innovation and Design (CBID) and Jhpiego, including a non-invasive mobile-based hemoglobinometers for anemia diagnosis (HemoGlobe).[9,10] Other potential

technologies include a hand-held blood pressure and pulse detector to screen for shock risk among pregnant women.[11] Many of these technologies are still being tested for efficacy or effectiveness as a single intervention. Once efficacy is established, implementation research is necessary to determine how these interventions can be packaged in a way that is feasible for easy use by lower-level health workers.

One area of antenatal diagnoses that has been neglected in low-resource settings is screening for sexually transmitted infections (STI). STIs, including HIV but also more prevalent and treatable infections like syphilis and gonorrhea, have previously been linked to adverse neonatal health outcomes, such as preterm birth and congenital abnormalities. For instance, a study from 1999-2001 conducted in our study site reported an OR of 4.7 (95% CI: 1.0-22.0) for very preterm delivery among women who tested positive for gonorrhea.[12] The need for such diagnostics will likely become greater with the increasing migration of young men from Nepal for migrant work, primarily to the Gulf States. In Nepal, there is evidence of high frequency of interaction with sex workers without condom use among migrant workers,[13] and also of high prevalence of STIs among migrant workers.[14] One study modeled the expected impact of migrant workers on HIV transmission rates in Far-Western Nepal, and reported an estimate of 7000 HIV infected individuals returning from India by 2015 and 12,000 Nepali migrant workers living with HIV in India.[15] Another study, conducted 14 years ago in far western Nepal, tested 97 migrant-returnees, and saw 10% prevalence in HIV and 25% prevalence in syphilis. 74% reported either sometimes or never using condoms in pre- or extramarital sex, which 79% of the men reported having.[16] In our study site, 31% of households

reported having at least one family member who works in India, Gulf countries, Southeast Asia, or Northeast Asia, and the rate goes down to 15% when excluding India. Gaydos and Hardick summarize the available point-of-care diagnostics for STIs, and highlight the inadequacy of many of the current diagnostics tools, either in accuracy or in cost.[17] It is necessary to conduct research on affordable diagnostic tools that can function in low-resource settings without compromising accuracy, and on behavior change communication among pregnant women and/or their husbands to receive screening and treatment.

Conclusions

During the era of the Millennium Development Goals, Nepal succeeded in reducing its neonatal mortality rate from 59 (in 1990) to 22 (in 2015) per 1000 live births. Despite this success, a large burden of neonatal death and of poorly enumerated stillbirths and neonatal morbidities still remain. Mortality and morbidity attributable to intrapartum-related complications have not fallen at the same pace as those attributable to other causes. To meet the neonatal mortality rate goal set by the Sustainable Development Goals of reduction to 12 per 1000 live births and to further address stillbirths and impairment, there needs to be a greater focus on effective interventions in the intrapartum period. This dissertation highlights the potential for targeting low-prevalence, but high-risk obstetric risk factors for primary prevention of intrapartum-related complications.

This dissertation summarizes numbers and words collected through my doctoral research. Putting that in context, those numbers and words represent true experiences of

women and infants in our study community, often ones that are as painful as a loss of a life. One mother interviewed for our study lost her infant during childbirth. She relayed to us, “I hope no mother will have to tolerate such a thing… I couldn’t do anything... I wish for nobody in the whole world to go through this.” We hope that this thesis will make a small contribution toward making this mother’s hope a reality.

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References

Appendix: Study implementation and data collection materials

NOMS Non-cephalic presentation substudy

Purpose

This substudy explores the epidemiology of intrapartum-related mortality and morbidity in rural Sarlahi District, Nepal, and assesses the feasibility of community-based, antenatal diagnosis of risk factors for intrapartum-related complications, including non-cephalic presentation, multiple gestation, and placenta previa. The description of the data collection pertaining to the epidemiology component can be found under Form 58 in the main MOO text.

Ultrasound study
This study estimated the diagnostic validity of non-cephalic presentation, multiple births, and poor placental position in rural Nepali communities. Community health workers with limited trained made home visits to pregnant women in the late third trimester, and conducted sonographic exams using a portable ultrasound machine.

Qualitative study
Women who had experienced a non-cephalic birth were interviewed to discuss their diagnostic and care-seeking behavior and perceptions pertaining to etiology and consequences of non-cephalic presentation. We also conducted focus groups with mothers in the community to obtain community perceptions and norms pertaining to non-cephalic presentation.

Ultrasound study procedures

Enrollment eligibility

We sampled pregnant women from seven VDCs that NOMS operates in, as those VDCs were located along a major road and closer to our main field office, making them easier to access by motorcycle than the other VDCs. An eligibility list of women who were gestational age of 32 weeks or above was produced by our data center (Form 91 – NCP Ultrasound Eligibility List), on a specified week for a specified VDC that the ANMs were making the home visits in. The form had address, NNIPSNUM, the woman's name, and her husband's name filled in by the data center, and the ANMs were instructed to fill in the status of the mother upon the visit: 1 for met, 2 for not met (write reason), 3 if the woman had already delivered the child, and 4 if the woman had already been examined during a previous visit to the VDC.

The ANMs visited the women on the list and consented and enrolled the mother in the study if she had not delivered the baby yet. Once the list for a particular VDC was exhausted, the ANMs would move onto another VDC to begin exams on a new list of women who were gestational age ≥32 weeks. We estimated that the ANMs would rotate through the designated seven VDCs in at minimum ten weeks, allowing them to return to the first VDC at around the time when there would be a new group of eligible mothers with gestational age ≥32 weeks. Women who had not delivered between the first and the subsequent time the ANMs visit a specific VDC and thus appeared on the eligibility list again were not given a second ultrasound exam.

Home-based ultrasound exams

Exam process

The ultrasound home visits were made by two ANMs at a time. A private location in the house was identified where the woman could lie down (on a cot/bed if available, mat on a floor if not). One family member was permitted to accompany the woman during the exam, if desired. To eliminate contamination of data, the ANMs were blinded to each other's exam; one ANM entered the location where the exam was to be conducted, while the other waited outside, and vice versa when it was the second ANM's turn to conduct her exam. Each ANM identified whether the pregnancy is single or multiple gestation, fetal position (cephalic, breech, transverse, or oblique), and placental position (no issue, low-lying/marginal/partial, complete, or cannot determine), and images that represented those diagnoses were saved on the ultrasound machine. They were also instructed to detect the fetal heartbeat, with instructions to refer the mother to a facility if the heartbeat was not detected. Form 90 was filled out by each ANM independently.

Form 90 –NCP ANM Ultrasound Assessment Form

General form administration rules

- The form is to be filled out for a subset of women enrolled in NOMS who are gestational age 32 weeks or above at the time of visit. The mothers will be from VDC 19 (Kabilasi), 20 (Pharhadawa), 21 (Laxmipur), 22 (Haripur), 28 (Pidari), 29 (Pipariya), or 30 (Janakinagar)
- On the NNIPS week that this form is filled out, the mother must have a gestational age greater than or equal to 32 weeks. All women eligible to receive an interview for this form will have a PEF, as Form 91 (NCP Ultrasound Eligibility Form) is printed based on PEF LMP.
- One mother will receive two ultrasound exams, with two different data collectors. Hence, there will be two forms filled out for each consenting mother / NNIPSNUM, with each form having a unique staff ID number and a unique number for the "Examining 1st or 2nd?" box.
- There will be two situations for which there will only be one form for a NNIPSNUM. 1) If the first data collector does not complete her exam, or 2) if the mother did not consent.

Heading

The NNIPS week and date of interview, worker ID, address (VDC, ward, sector, and household number), the woman's NNIPSNUM, and the woman's name should all be filled out. If the data collector is the first one to do the exam, the "Examining 1st or 2nd?" box should be filled out with a "1" and the subsequent "Consent?" box should be filled out with a "1" for "yes" or a "6" for "No." If the response is "6" (woman did not consent), the second data collector will not fill out a form.

If the woman is consented by the first data collector, the second data collector will write "2" in the "Examining 1st or 2nd?" box" and a "1" in the "Consent?" box.

If the exam was completed (see question at the very bottom), the form must have a start time of exam.

If the exam was not completed (see question at the very bottom), the form may or may not have a start time of exam. If the first data collector did not complete the exam, there will be no second form for this NNIPSNUM.

Q1: Multiple pregnancy? The options are "0" for "No," and "1" for "Yes."
For response "0," the second box of Q2 and the second box of Q3 must be blank.
For response "1," both boxes of Q2 and both boxes of Q3 must be filled out.

Q2: Non-cephalic presentation? The options are "1" for "Cephalic," "2" for "Breech," and "3" for "Transverse," "4" for "Oblique."

Q3: Fetal heartbeat? The options are “0” for “No heartbeat detected,” and “1” for “Heartbeat detected.”

Q4: Placental position? The options are “1” for “anterior,” “2” for “posterior,” “3” for “right lateral,” “4” for “left lateral,” “5” for “superior/fundal,” “6” for “placenta previa / low lying placenta,” and “9” for “cannot determine.”
If the response is “6,” Q4a must be filled out.
For all other responses, Q4a must be blank.

Q4a: Placenta previa status. The options are “1” for “low-lying, marginal, or partial previa,” “2” for “complete previa,” and “9” for “cannot determine.” This should be filled out if response to Q4 was “6.”

Notes: There is a write-in section called “Notes” for additional notes the data collector may want to report.

Exam completed? The options are “0” for “No” with a write-in answer to indicate why, and “1” for “Yes.”
If the response is “1,” start time of exam at the top of the form and the “If Y, # of images taken” box must be filled out.

If Y, # of images taken: The number in this box must be less than 10.

- - -

Post-exam referral

If at least one of the two ANMs detected fetal malposition and/or multiple gestation, the mother was instructed to make a visit to a birthing center to confirm diagnosis and also to make preparations to deliver at the nearest CEmOC facility, if possible, or at least a nearby birthing center if not. Placenta previa is a more dire medical condition that needs to be managed prior to labor. Women with suspected placenta previa were notified of the possible diagnosis and Form 92 was filled out. On the same day as the exam, the ANMs sent the images taken for a suspected placenta previa case by e-mail to gold standard readers based in Kathmandu. The ANMs were instructed to also send a text message to our gold standard reader to notify him that the images were sent. The gold standard readers were instructed to provide their diagnosis within three days of notification. The ANMs then returned to the household the next business day to notify the mother of the gold standard diagnosis. Mothers who had no danger signs detected received counseling on the importance of antenatal care visits, birth preparedness, and facility-based deliveries. They were also provided a list of nearby birthing centers, strongly emphasizing that the ANMs not detecting danger signs does not preclude them from having a complicated delivery. As this study was conducted to assess the validity at which the ANMs can detect the risk factors, the referral messaging was provided with the caveat that the ANMs had received minimal training and that the mothers should seek care to confirm diagnoses.

Form 92 - NCP Ultrasound Rapid Assessment Log
This form was a job aide, not a form with data entry.

Heading
The NNIPS week and date of interview, worker ID, address (VDC, ward, sector, and household number), the woman's NNIPSNUM, and the woman's name should all be filled out.

Box: "Reason" The options are 1 for "suspected placenta previa" and 2 for "suspected abnormality." There is a write-in section that could be used as necessary to describe what the ANMs observed.

Box: "SMS sent?" The options are Y/N. Once the ANMs sent a text message to our designated gold standard reader, the ANMs were instructed to fill the box with "Y."

Box: "Images sent?" The options are Y/N. Once the ANMs sent an e-mail with the images attached to our designated gold standard reader, the ANMs were instructed to fill the box with "Y."

Response from IOM: The ANMs were instructed to fill in the write-in section with whatever diagnosis was received from the gold standard reader immediately upon receiving that information.

a) If placenta previa check, visit made (Y/N)? If the ANMs had a suspected placenta previa case, they were instructed to return to the home, regardless of whether the final diagnosis was positive or negative. The ANMs were instructed to write in "Y" and the date of the revisit immediately after the visit was made.

b) If placenta previa check, visit made (Y/N)? If the ANMs had a suspected an abnormality, they were instructed to return to the home only if an adverse abnormality was identified by the gold standard reader. The ANMs were instructed to write in "Y" and the date of the revisit immediately after the visit was made, if and only if the revisit was necessary.

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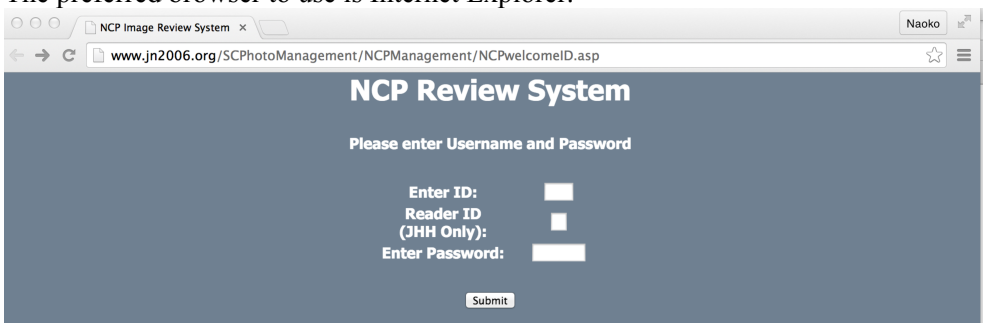
Gold standard assessment

The gold standard readers were instructed to log in to an image review website set up by the data manager. Instructions provided to the reviewers are found below.

1)
Go to link to get to the home page of the image review system:
http://www.jn2006.org/SCPhotoManagement/NCPManagement/NCPwelcomeID.asp
The preferred browser to use is Internet Explorer.



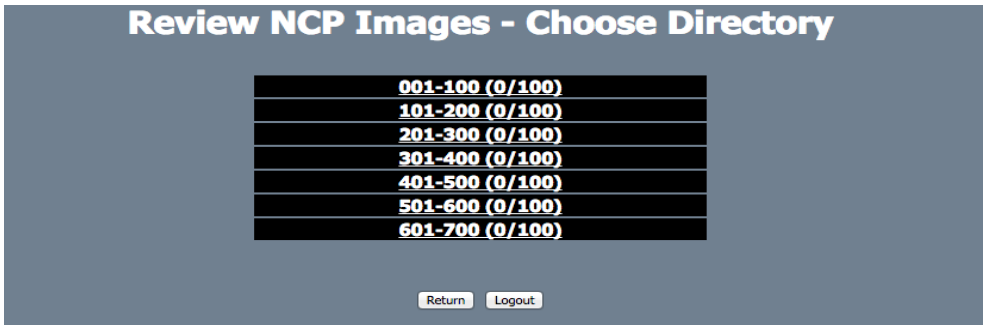
2)
Enter ID (passwords provided individually).

IOM
R. Ghimire: ID # 111, leave Reader ID blank
S. Paudel: ID # 222, leave Reader ID blank

JHH (in alphabetical order)
C. Bird: ID # 555, Reader ID 1
K. Blakemore: ID # 555, Reader ID 2
J. Laferriere: ID # 555, Reader ID 3
R. Mazza: ID # 555, Reader ID 4
B. Ryan: ID # 555, Reader ID 5
S. Trebes: ID #555, Reader ID 6

3)
On the next page, click “Review Images.”

4)
The exams conducted by the ANMs were grouped in 100s for review. The image below as an example shows that 700 exams have been uploaded. The (0/100) represents that this reviewer has currently conducted reviews for 0 of the 100 exams in that group of images.

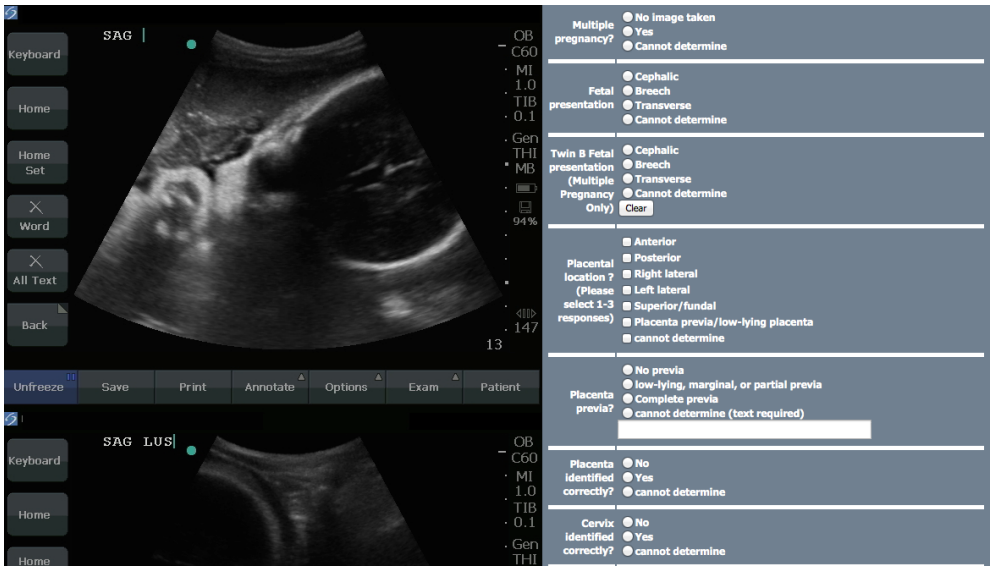


The images were divvied up as follows.

Exam numbers	Nepal IOM	JHH
001-100	Ghimire	Bird
101-200	Paudel	Blakemore
201-300	Ghimire	Laferriere
301-400	Paudel	Mazza
401-500	Ghimire	Ryan
501-600	Paudel	Bird
601-700	Ghimire	Blakemore
701-800	Paudel	Laferriere
801-900	Ghimire	Mazza
901-1000	Paudel	Ryan
1001-1100	Ghimire	Trebes
1101-1200	Paudel	Trebes
1201-1300	Ghimire	Bird
1301-1400	Paudel	Blakemore
1401-1500	Ghimire	Laferriere
1501-1600	Paudel	Mazza
1601-1700	Ghimire	Ryan

Click on the link for the group of images you are responsible for.

5)
You will come to the review screen. All the images on the same screen come from the same exam/same mother. The webpage is a "split screen," in that you can scroll the left side to get all the ultrasound images and you can scroll the right side to get to all the assessment questions.



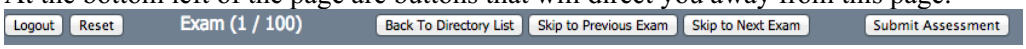
6)

Please see below descriptions of each of the assessment questions.

- Multiple pregnancy?
    - If there's no image that has labels pertaining to multiple birth, click No image taken. If the ANM believed that it was a multiple pregnancy, they were required to take an image that shows a body part of one fetus and a body part of another fetus, and to label it appropriately as "Twin A" and "Twin B" respectively. If such image was taken and you agree that it is a multiple pregnancy, click Yes. If the images that the ANM labeled as twins do not look definitive, click Cannot determine.
- Fetal presentation
    - Based on the images, please click on whether you believe the fetus is cephalic, breech, or transverse, or click cannot determine if the images are not definitive.
    - If you believe this is a multiple pregnancy, please fill out the first fetal presentation question for Twin A, and the second fetal presentation question for Twin B.
- Placental location?
    - This question is just meant to get a sense for whether or not the ANMs are roughly understanding where the placental location is, and the question has no clinical implications. As the placenta could technically be anterior or posterior AND right lateral or left lateral AND superior or low-lying, you can choose up to 3 check boxes regarding the placental location. If the images are too poor for you to determine the placental location at all, click cannot determine.

- Placenta previa?
    - Based on the images, please click on whether you believe this is a case of no previa, low lying/marginal/partial previa, complete previa, or cannot determine. If you cannot tell from the image, please explain why in the text box.
- Placenta identified correctly?
    - The ANMs are required to label the placenta on the images ("PL"). Please click No, Yes, or Don't Know as to whether or not the placenta was identified correctly.
- Cervix identified correctly?
    - The ANMs are required to label the cervix on one of the images ("CX"). Please click No, Yes, or Don't Know as to whether or not the cervix was identified correctly.
- Overall quality of images
    - This is a subjective question. From examining the images, please indicate whether you though the images were poor, adequate, or good for you in making the diagnoses.
- Comments, if applicable
    - If you have any comments, please write in the text box.

7)
At the bottom left of the page are buttons that will direct you away from this page.



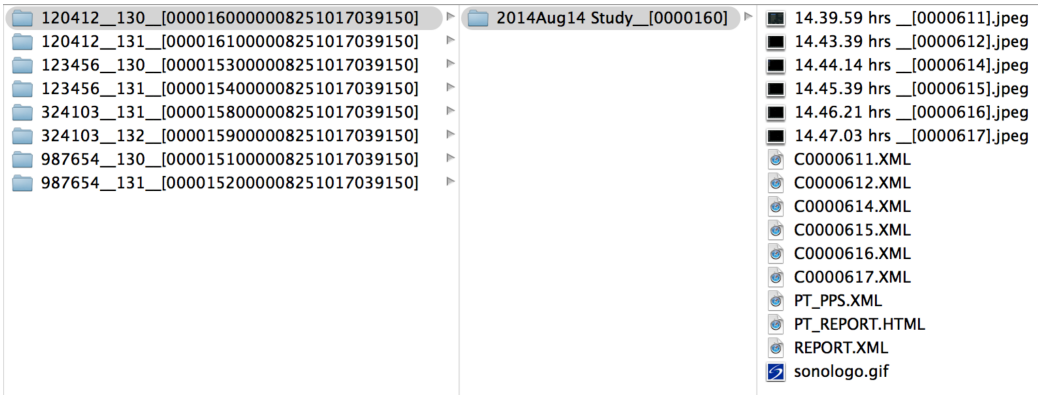
Clicking "Submit Assessment" will save your responses and move you to the next exam. "Back to Directory List" will take you back to the page that is shown on Step 4. Skip to previous and next exam will do just that. Reset will clear all your answers on this page. Logout will log you out. There will also be a counter, next to the "Reset" button. In this example, it shows that you are on exam #1 of 100.

8)
When you log out and log back in, it will start you at the last completed exam rather than the first incomplete exam. So just click submit assessment and move onto the next exam.

- - -

Image management protocol

1) The Nanomaxx ultrasound machine produces a folder for each exam (labeled with NNIPSNUM + Worker ID + set of extraneous numbers), then a subfolder for date of exam, then images labeled with time of exam (plus other extraneous files).



The exam folders will be downloaded as is onto a Google Drive folder named "NCP ultrasound images" on the Desktop of the NNIPS FHQ computer (logged in as user "nnips.ultrasound") by the ANMs, organized into folders by NNIPS week.

2) The study coordinator will download the folders onto her computer from Google Drive (when not in the field).

3) The study coordinator will run a code for each NNIPS week folder. The code will 1) move all the files from the subfolder to the main folder, 2) delete unnecessary .xml, .html, .gif files and the now empty subfolder, and 3) rename the folders and image files. After the renaming, each folder will be labeled NNIPSNUM (6 digits) + two underscores + Worker ID (3 digits) (= first 11 digits of the folder name that the ultrasound machine automatically produces). The images inside those folders will be named with the same name as the folder, followed by one underscore and a single-digit image number (just produced by count).

4) After renaming all the files, the study coordinator will then organize by hand the exam folders into groups of 100. Parent folder will be labeled as "1-100" "101-200" "201-300" etc. At this point, the study coordinator will also make note to NOT include any exams that should be excluded from review (e.g. cases where only one exam of two were conducted, images were broken for whatever reason, etc.)

5) The study coordinator will then re-upload those exam folders onto a Google Drive folder within the "NCP Ultrasound Images" folder called "NCP Review Images." Data

manager will then take those folders and place them on the server for gold standard assessment. Each exam folder's worth of images will be displayed on a single gold standard assessment page.

Copies of all files to stay on: 1) NNIPS FHQ Computer (in original form), 2) USB Drive that the ANMs are using to download/upload (in original form), 3) Google Drive (in original & simplified/renamed forms), 4) study coordinator's computer (in original & simplified/renamed forms).

Applescript code

```
with timeout of (30*60) seconds
tell application "Finder"

#Step 1: Select the week folder you're working with and move all the files into the folder for each exam

set weekfolder to (choose folder)
repeat with theTopFolder in folder weekfolder
set subfolder to folders of theTopFolder
repeat with each_folder in subfolder
move every item of each_folder to theTopFolder with replacing
end repeat
end repeat

#Step 2: Delete all the unnecessary files that the ultrasound machine produces

delete (every item of entire contents of folder weekfolder whose name ends with ".xml")
delete (every item of entire contents of folder weekfolder whose name ends with ".html")
delete (every item of entire contents of folder weekfolder whose name ends with ".gif")
delete (every item of entire contents of folder weekfolder whose name starts with "2015")

#Step 3: rename the exam folder so it only has NNIPSNUM and staff ID

repeat with theTopFolder in folder weekfolder
set name of theTopFolder to text 1 thru 11 of (get name of theTopFolder)
end repeat

#Step 4: rename all the image files and delete the patient info entry page

set a to every folder of folder weekfolder
repeat with aa in a
set folderName to name of aa
set counter to 0
set all_files to (every file in aa)
repeat with ff in all_files
set ff's name to (folderName & "_" & counter as string) & ".jpeg"
set counter to counter + 1
end repeat
end repeat
delete (every item of entire contents of folder weekfolder whose name ends with "_0.jpeg")
end tell
end timeout
```

Qualitative study procedures

In-depth interviews

We used responses from Form 58 to identify women who reported a non-cephalic delivery between two and twelve months prior to the time of interview. We did not place any geographic limits, meaning all women from the 34 VDCs in which NOMS operates were included. The following protocol was followed during the first set of interviews: We created a "two-by-two" recruiting procedure, with a quarter of the enrolled women having experienced no adverse outcomes (stillbirth or death of a neonate within the first week of life) and delivered at home, another quarter having experienced no adverse outcomes and delivered in a facility, another quarter having experienced an adverse outcome and delivered at home, and another quarter having experienced an adverse outcome and delivered at a facility. We also enrolled a female family member who contributed to decision-making regarding care during labor and delivery, to be interviewed separately to get the perspective of a household decision-maker. We first tried to recruit the mother-in-law, as they are considered prominent household decision makers in this community, but we also allowed for their mothers, sisters, and sister-in-laws as eligible participants. The women and the selected family member consented separately, and either individual can participate without the other participating.

After the eighth pair was interviewed, the content of the interviews were reviewed. At this point, we determined that the pregnant woman's role in care-seeking decisionmaking during labor and delivery is minimal in our community. Thus, we changed the study design to just interview the female decisionmaker in the household. If such an individual is not available in the household, the woman will be interviewed instead. If the female decisionmaker chooses to have the woman sit in on the interview as well, we allowed for the two interviewees to sit in on one interview. As an equal number of eligible women are not available in the "two-by-two" categories, we still sampled from each of the categories as evenly as possible to assure a wide range of experiences to be collected through the interviews, but the final number of women sampled from each category may not be the same across the four categories. The interviews were recorded with permission from the interviewees.

For each IDI, the interviewer received a form (Non-cephalic Presentation – In-depth Interview Form). Prior to the interview, the form was filled out by the study coordinator with the following information: Interview #, whether the interviewee had a home/facility delivery, whether the baby in question was alive or dead, the address, NNIPSNUM, woman's name, and her husband's name were filled out. The interviewer was then instructed to fill out her worker ID, date of the interview, who she was interviewing (1 for woman herself, 2 for her mother-in-law, 3 for other and a write-in slot to identify who, 4 for could not find person to interview), whether the person was consented (1 for yes, 6 for no), and the recorder number (each digital recorder had an identifier number).

The interviewers were asked to answer the following questions on the form:

1) Interview Summary –1) experience during labor and delivery, 2) whether they knew baby was upside down before labor, 3) what care they sought specific to baby being upside down, 4) their perceptions toward upside down babies.
2) Description of home/interview environment
3) Description of person you interviewed
4) Other (anything else)
5) Summary of background section in interview - the first few questions on the interview guide consisted of questions regarding the interviewee's age, number of children, etc., and the interviewers were asked to summarize the content rather than transcribe word-for-word.

Focus groups

In order to better understand how the general community perceives the issue of non-cephalic presentation, we also conducted two focus group discussions (FGD) with younger women (inclusion criterion: at least two children, with at least one under five years of age) and with older women (inclusion criterion: at least one grandchild) respectively. We received informed verbal consent from all individuals, and the FGD was recorded with permission. 6-8 participants were recruited for each focus group. The focus groups were conducted in NOMS VDCs. No particular selection criterion was placed on VDCs, other than excluding VDCs that we were not operating our ultrasound substudy in. The VDC selection was mainly based on the size of the VDC NNIPS office and its ability to host a focus group of the size mentioned above.

The facilitator was asked to fill out a form (NCP Focus Group Form) to record information on the participants of the focus groups. For the mothers' groups, the form required input of the date of the interview, VDC #, focus group #, the facilitator's staff ID, the notetaker's staff ID, and for each participant, whether they consented or not, age, number of children (must be at least two), age of the youngest child (must be less than five), and who she was consented by (staff ID of the consenter). For the grandmothers' groups, the same information was asked, except instead of information on children, she was asked the number of grandchildren (must be at least one) and age of the youngest grandchild. Both forms also had a section for the facilitator to describe briefly the location the focus group was held.

Transcription / translation

IDI and FGD recordings were first transcribed (handwritten) from Maithili to Nepali by the interviewers/facilitators themselves. The transcripts were sent to the research coordinator Shakuntala Singh, based in our office in Kathmandu, who then distributed the de-identified transcripts to Nepali translators for translation into English. Recordings, transcripts, and translations were all de-identified, and labeled with an interview number.

Data storage

The recordings were saved on an external hard drive that was stored in a locked cabinet at the field office, and were deleted from the recorders immediately after the interviewers finished transcription. The recordings and transcripts were also sent to Kathmandu by vehicle on a USB key for the data center to upload on the NNIPS server.

- - -

Quantitative data collection form

Data collection forms that were primarily from the parent study not included

NEPAL Oil Massage Study – Supplement for Non-Cephalic Presentation

MBAF Address: ☐☐☐☐☐☐☐ **Date** ☐☐-☐☐-☐☐

Mother NNIPSNUM: ☐☐☐☐☐☐ **Twins or triplets?** ☐
0 = No 1 = Yes

1	Have you heard of ultrasound / video x-ray before?	0 = No (Skip to Q3) 1= Yes	☐
1a	To the best of your knowledge, what is ultrasound/video x-ray used for? (up to 3 responses)	1= to check on the health of the baby 2= to check on the health of the mother 3 = to determine the position of the baby 4= to determine the sex of the baby 5= other _____ 9= I don't know	☐☐☐
1b	How did you learn about ultrasound/video x-ray (up to 3 responses)	1=Family members 6=Local Doctor 2=Neighbors/friends 7=MBBS Doctor 3=TBA/Chamain 8 = other _____ 4=CHV/VHW/MCH worker 9=Don't Know 5=ANM/HA/CMA/Staff Nurse	☐☐☐
2	Did you have an ultrasound exam /video x-ray during this pregnancy?	0= No (skip to Q3) 1= Yes	☐
2a	How many ultrasound exams did you have during this pregnancy?	1-8 times 9 = Don't know	☐
2b	Where was the most recent ultrasound done?	0= by Balposhan staff (skip to Q3) 1= Sarlahi _____ 2= Birganji 3= Janakpur 4= other _____	☐
2c	Why did you have the ultrasound?	0= advised by the doctor 1= to check on the health of the baby 2= to check on the health of the mother 3 = to determine the position of the baby 4= to determine the sex of the baby 5= other _____	☐☐☐
2d	How much did the most recent ultrasound exam cost?	Write the number in rupees 9999=Don't know	☐☐☐☐

#	Question	Codes	
3	What part of your baby's body came out first?	0= C-section 1= Head 2= Foot/feet 3= Arm(s) 4 = Umbilical cord 5 = Buttocks 6 = Other (write on the line) 9 = Don't know If any box has "2, 3, 4, 5, or 6" go to Q3a, else go to Q4	Baby 1 Baby 2 Baby 3 ☐ ☐ ☐ _____ _____ _____
3a	Did you know prior to delivery that the baby was not positioned with its head down?	0=No (Skip to Q4) 1=Yes	☐
3b	How did you find out? (Up to three responses)	0 = ultrasound/video x-ray (Balposhan) 1 = mother self-examination 2 = physical assessment by traditional healer 3 = physical assessment by traditional birth attendant 4 = physical assessment by an auxiliary nurse midwife 5 = physical assessment by doctor or nurse 6 = ultrasound/video x-ray 7 = other → Describe in the lines to the right - - - ->	☐ ☐ ☐ _____ _____
3c	Having found out about your baby's position, did you make any preparations prior to delivery? (Up to three responses)	0= No 1= consult from facility/doctor 2= planned to deliver at hospital/facility 3= made financial arrangements 4= doctor/ nurse/trained health worker tried to flip baby 5= Traditional birth attendant tried to flip baby 6= other → Describe in the lines to the right - - - ->	☐ ☐ ☐ _____ _____
4	Did you know prior to delivery what gender your baby/babies would be?	0=No → Q5 1=Yes	☐
4a	How did you find out?	1 = ultrasound 2 = traditional methods	☐

If multiple birth → Go to Question 5, else STOP

5	Did you know prior to delivery that you're having multiple babies?	0=No → STOP 1=Yes → Q5a	
5a	How did you find out? (up to 3 responses)	0= ultrasound/video x-ray (Balposhan) 1= mother self-examination 2= physical assessment by traditional healer 3= physical assessment by traditional birth attendant 4= physical assessment by an auxiliary nurse midwife 5= physical assessment by doctor or nurse 6= ultrasound/video x-ray 7= other → Describe in the lines to the right - - ->	☐ ☐ ☐ _____ _____
5b	Having found out about having multiple babies, did you make any preparations prior to delivery? (up to 3 responses)	0=No 1= consult from facility/doctor 2= planned to deliver at hospital/facility 3= made financial arrangements 4=other → Describe in the lines to the right - - ->	☐ ☐ ☐ _____ _____

Facility survey data collection form

Date of interview:
With what level staff member:

Facility survey – NCP Study

Facility details	Name ____ Facility Type ____ VDC ____ Ward ____ Sector ____ # of deliveries per month ____ % ANC 4 last month: ____	
Staff (write number in facility)	MBBS: ____	AHW / CMA: ____
	HA: ____	ANM: ____
	Staff nurse: ____	*Total SBA:* ____
BEmOC / CEmOC capacity (0 = No 1 = Yes)	Parenteral antibiotics ____	Parenteral oxytocics ____
	Parenteral anti-convulsants ____	Manual removal of placenta ____
	Removal of retained products of conception ____	Assisted vaginal delivery ____
	Cesarean section ____	Blood transfusion ____
Newborn resuscitation capacity	Trained staff ____	Bag and mask (infant size) ____
	Tube and mask (infant size) ____	Suction bulb for mucus extraction ____
Drug availability	Misoprostol ____	
Contraceptive availability	Depo-provera ____	Oral contraceptives ____
	IUD ____	Norplant ____

Date of interview:
With what level staff member:

Which facility do you refer patients to?	Name:	Location:
Where is the nearest facility for cesarean section?	Name:	Location:
Availability of vehicle for referral / price		

Non-cephalic presentation
How does the facility usually handle a baby who is not coming out head first during delivery?

Has anyone in your staff been trained to do deliveries for a baby who is not coming out head first?

Twins
How does the facility usually handle twins?

Has anyone in your staff been formally trained to conduct twin deliveries?

Placental issues
How does the facility usually handle problems with the position of the placenta?

Date of interview:
With what level staff member:

Other

Can you tell me about what the facility does when a mother experiences prolonged and/or obstructed labor that has not been discussed already?

Ultrasound use

Can you tell me about ultrasound use among the patients you see at your facility? (prompts: What do people use ultrasound exams for? Do you refer for ultrasound exams?)

Where is the nearest location with an ultrasound?

Ultrasound Study data collection forms and job aides

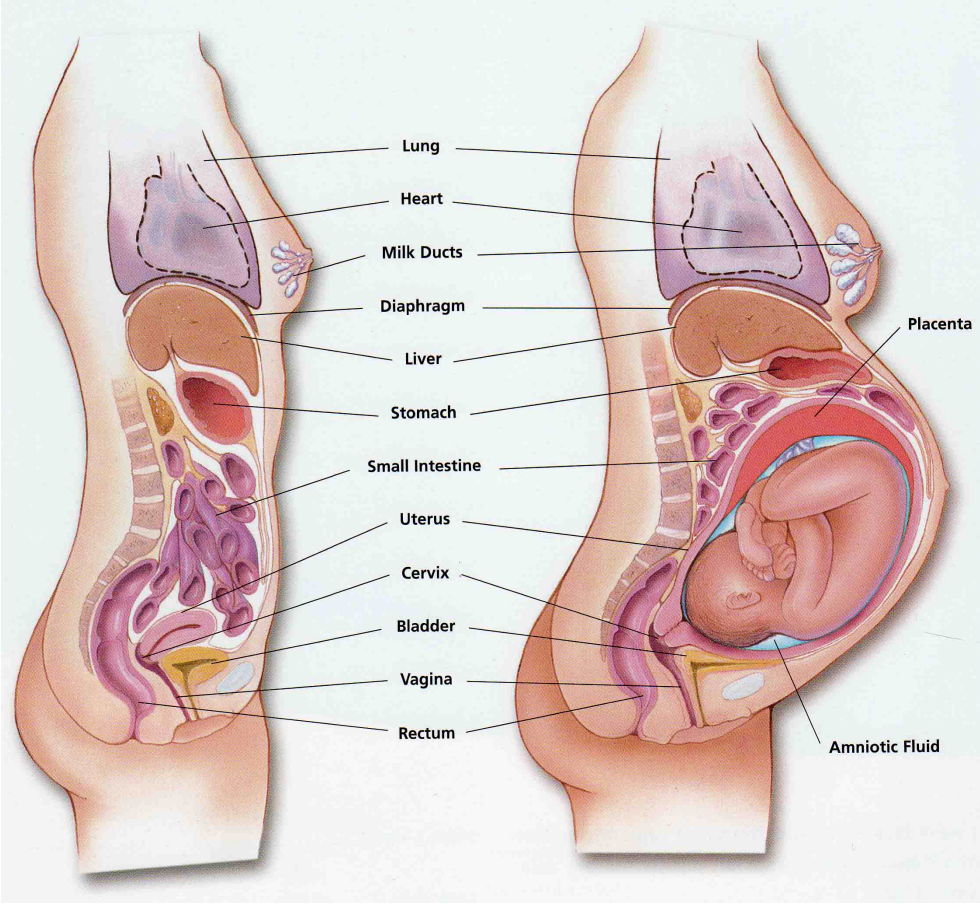
Ultrasound training manual

NCP Ultrasound Substudy Training Manual

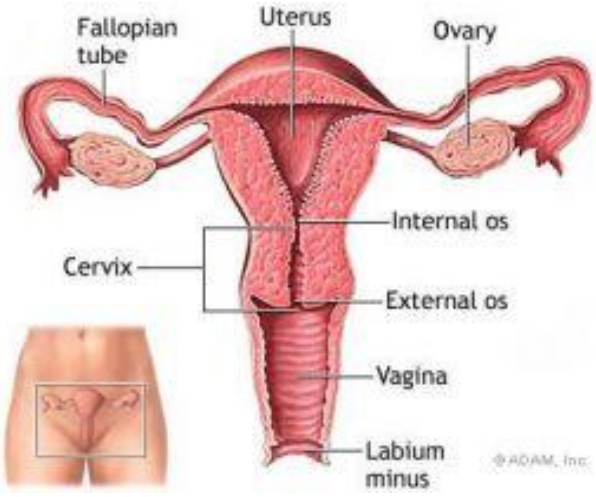
1) Clinical aspects related to the NOMS ultrasound substudy

Anatomy

See below images of anatomical parts of the female reproductive system.



The location of the internal os is of a particular importance for this study, as the placenta overlapping or covering the internal os defines placenta previa.



Risk factors of interest

Non-cephalic presentation

Non-cephalic presentation is defined as a baby presenting with body part(s) other than its head first. The baby can be breech (presenting with its bottom / feet first) or transverse (horizontal to the mother). Non-cephalic presentation can be dangerous, as the mother can experience obstructed and/or prolonged labor due to the difficulty with the baby exiting the mother. Obstructed and/or prolonged labor can lead to asphyxia in the baby and cause fresh stillbirth or early neonatal death. Certain non-cephalic presentation, like footling breech, is especially dangerous due to higher risk of cord prolapse. Transverse presentation also has a high risk of cord prolapse. Another terminology for non-cephalic / cephalic is non-vertex / vertex.

Proper care at delivery. Some breech babies can be delivered vaginally by a birth attendant that is specifically trained in assisting deliveries for these fetuses (skilled birth attendant (SBA) training). However, there is high likelihood of complications, such as asyphxia, spine injuries, and trauma to the limbs. It is best if fetuses are delivered either by cesarean section, or delivered in a facility that has an option for cesarean section, so the mother can be transferred to an operating room if necessary. Incomplete breech (also known as footling breech) and transverse babies should be delivered by cesarean section, as they have high risk of complications, such as cord prolapse.

Figure: Cephalic presentation

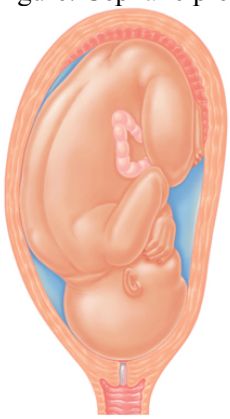
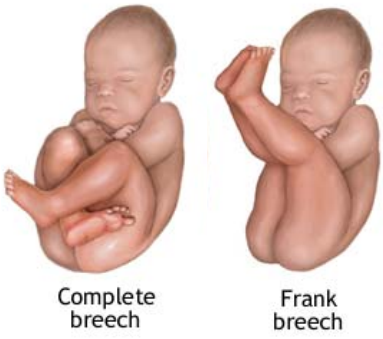
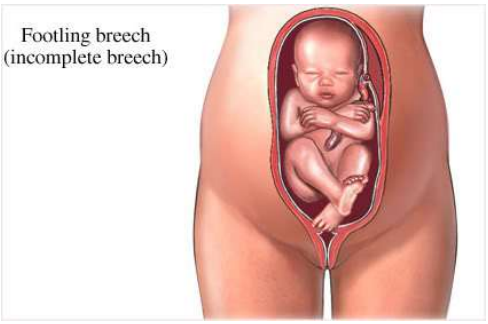


Figure: Possible breech presentations





*A foot is located below the buttocks in footling breech.

Figure: Transverse presentation

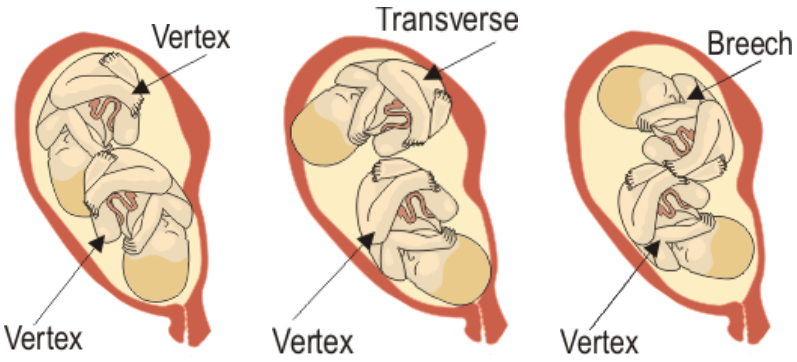
Multiple gestation

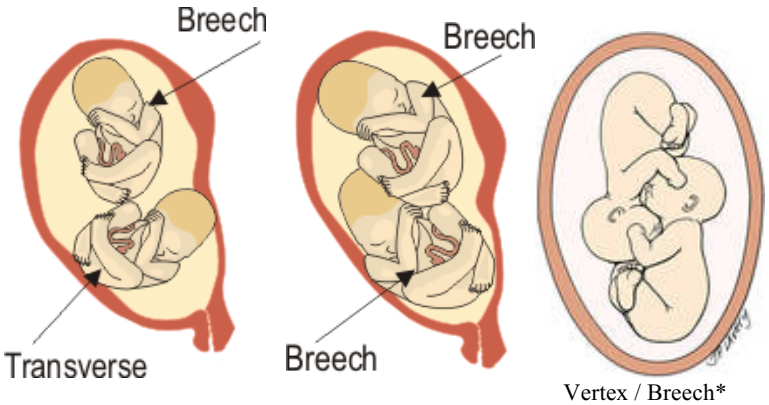
Multiple gestation is defined as having more than one fetus in the womb (e.g. twins). Multiple gestation can be dangerous for two reasons. One, twins tend to be small and/or preterm, making them more susceptible to mortality and morbidity. Two, if one or the other twin is in non-cephalic presentation, it may be difficult for them to exit the womb and the mother may experience obstructed and/or prolonged labor. Usually, the second twin is more in danger of poor outcomes.

There are certain twin presentations that are more dangerous than others. If twin A (the twin that is closer to the cervix) is breech and twin B (the twin that is farther from the cervix) is cephalic, there is the possibility of interlocking heads, or the twins' heads lining up together in a way that prevents the twin from moving. Any transverse baby has a risk of cord prolapse. The first twin being non-vertex also means that the babies will have higher risk.

Ideal care at delivery. Twins can be delivered vaginally by a trained birth attendant. However, there is likelihood for complications, such as retained second twin (the second twin taking a long time to exit the womb, leading to hypoxia). It is best if fetuses are delivered in a facility that has an option for cesarean section, so the mother can be transferred to an operating room if necessary. Also, it is important to deliver the babies in a facility, as small and/or preterm babies have high risk of poor outcomes.

Figure: Potential presentations of twin babies





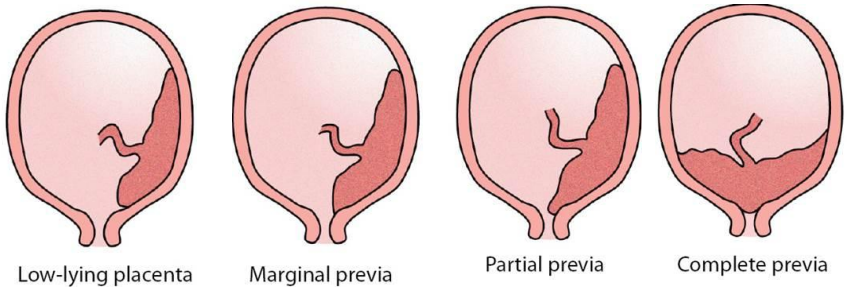
Vertex / Breech*
*This image is an example
of interlocking heads.

Placenta previa / poor placental location

Placenta previa is defined as the placenta partially or fully covering the internal os, or more simply, when the placenta is partially or fully blocking the fetus' way out of the womb. Placenta previa can lead to antepartum hemorrhage, with the risk being higher the more placenta covers the internal os. We expect placenta previa to occur in 0.5-1% of the mothers, and low-lying placenta to occur in 1-2% of mothers. In the third trimester, the placental location may be hard to detect if they are in a posterior location.

Proper care at delivery. Women with placenta previa are recommended to take bed rest, and refrain from strenuous physical activity, including sexual activity. For complete or partial placenta previa, the fetus should be delivered by cesarean section. For women who have marginal placenta previa or a low-lying placenta, it would be best to deliver somewhere with cesarean section capacity in case a vaginal delivery does not go well.

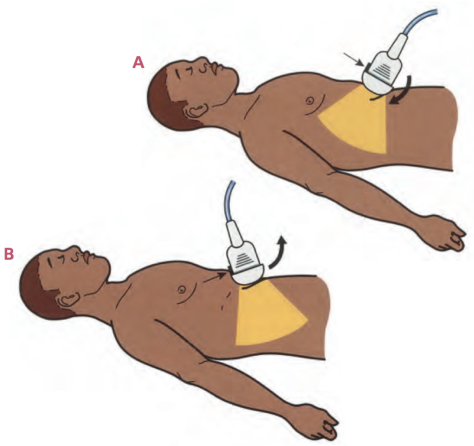
Figures: Placenta previa, types I-IV



2) Ultrasound

Ultrasound machines emit sound waves at a high frequency. The sound waves bounce back from parts of the body, and those sound images are converted into electric signals which are then converted to images.

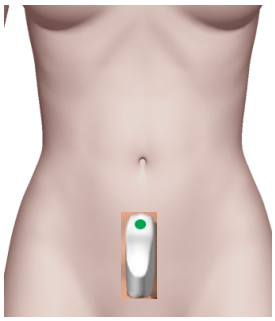
The image will change depending on where you place the probe and what direction the probe is facing. By tilting the probe in one direction versus another, the image that is displayed differs, as shown on the figure below.



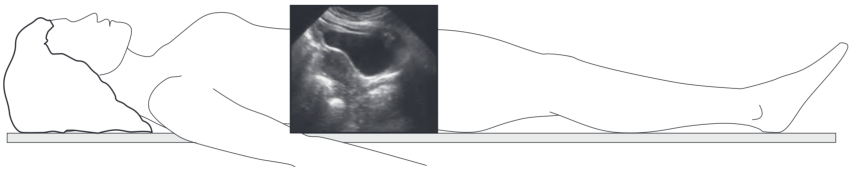
The mother should be lying down in a comfortable position. The assessor should sit on the mother's right side, and should be facing the mother's head. Gel must be placed on the area you are scanning. The gel removes any air between the probe and the skin that may obstruct the sound waves. An aqueous (water-based) gel should be used, and the gel should be placed on the body. Tell the mother to report any discomfort. If the exam is going too long, you should have the mother rotate on her side and/or take a break
Direction of the probe

Sagittal

The sagittal placement of the probe is when the probe is facing vertically. Traditionally, the dot on one side of the probe represents the left side of the screen and should be facing the mother's head. The assessor should tap her finger on the dot side of the probe to confirm whether the left side of the screen shows movement. (The probe will be checked by the study coordinator on a weekly basis to make sure the settings have not been altered.) The probe should initially be placed over the lower uterine segment, as indicated by placement between the pelvic bones.

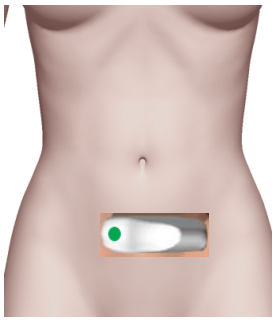


When you examine the non-pregnant patient with the probe placed sagitally, the image of the uterus would look like this. The bladder overlies the uterus and appears anechoic ("black").

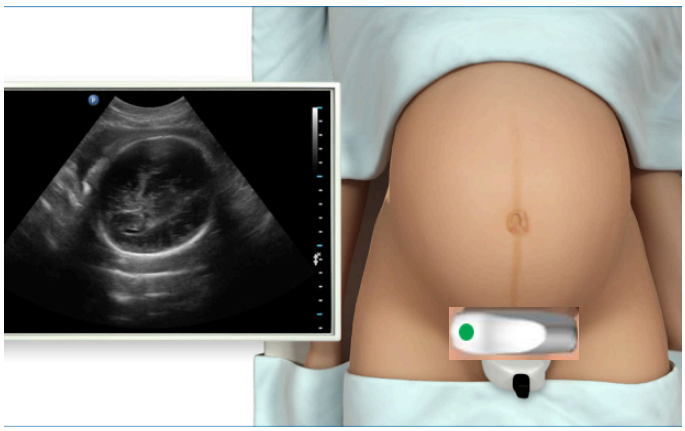


Transverse

The transverse images of the uterus are obtaining when the probe is placed horizontally. The dot on the probe (which should be representing the left side of the screen) should be facing the mother's right side. The probe should initially be placed over the lower uterine segment, as indicated by placement between the pelvic bones.



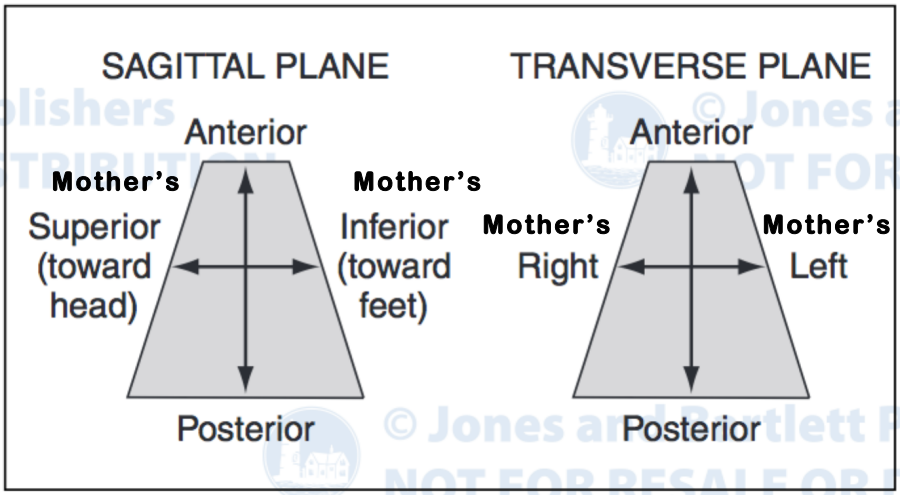
When you examine the mother with the probe placed transverse, the image of the uterus would look like this (the picture below is when the baby is cephalic).



Reading sonograms

The sonograms are black and white images. The color depends on what the sound waves are bouncing against. Anechoic (or not echoic) means that there is nothing that is bouncing back the sound waves. They show up as black in the image. Liquid (such as amniotic fluid, urine in the bladder, unclotted blood and blood vessels) will show up as anechoic / black. Hyperechoic means that there is something very solid that the sound waves are bouncing off of. They show up as white in the image. Bone shows up as hyperechoic / white. Hypoechoic would refer to echoes from soft tissues that bounce back the sound waves somewhat less. They show up as grey in the image.

What is seen at the top of the screen is anterior, or closer to the mother's front side, and what is seen at the bottom of the screen is posterior, or closer to the mother's back side. If the probe is placed sagitally, the mother's head side (superior) is on the left side of the screen, and mother's feet side (inferior) is on the right side of the screen. If the probe is placed transversely, the right side of the mother is on the left side of the screen / image, and the left side of the mother is on the right side of the screen / image.

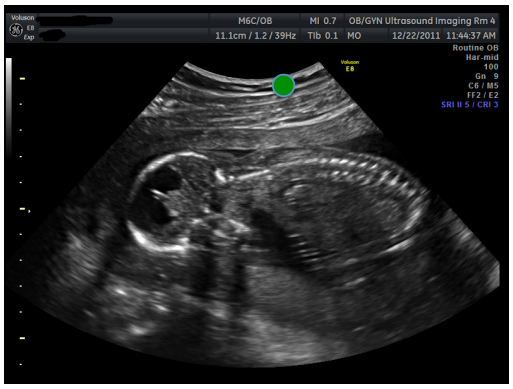


Fetal presentation

If the probe is placed transverse and over the lower uterine segment, a section of the fetus will be visible on the screen. If the baby is cephalic, the fetal head should be visible. If the fetus is breech, the legs, feet, and/or buttocks should be visible. If the fetus is transverse, the assessor should scan through the mother's abdomen from one side to the other to see if they are able to trace the fetus's spine and body from head to buttocks. To capture a transverse fetus on an image with a probe in transverse position, one image should capture some part of the head and some part of the body.

If the probe is placed sagittally, a cephalic positioned fetus should have its head on the right side of the screen (see figure below).

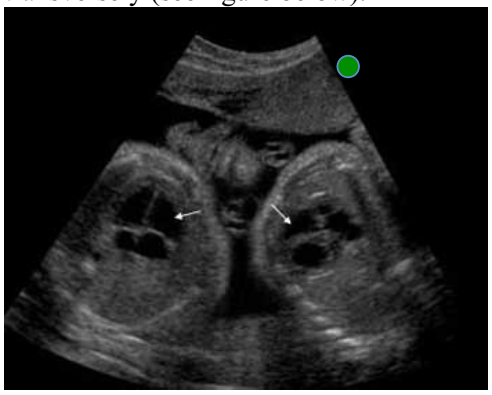
In a sagittal view, non-cephalic fetus should have its head on the left side of the screen (see figure below).



Multiple gestation

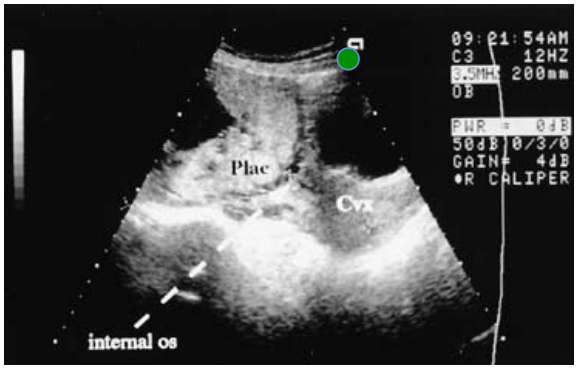
In all pregnancies, you will need to scan through the entire uterine cavity to confirm twins. The assessor should identify two heartbeats if multiple gestation is suspected. With twins, the fetuses could be positioned in any combination of cephalic, non-cephalic, and transverse positions.

This image shows the hearts of two twins, taken with the ultrasound transducer placed transversely (see figure below).



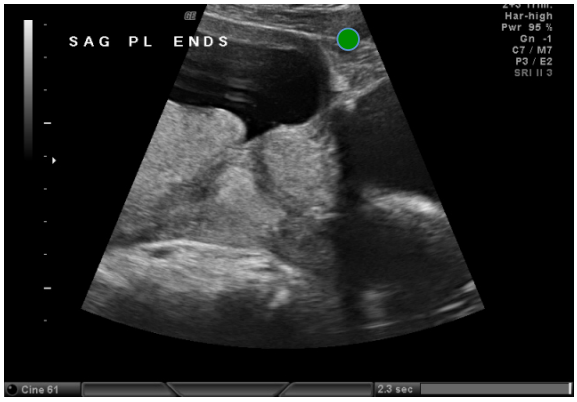
Placenta previa / poor placental location

Complete placenta previa (type IV) will have the placenta fully covering the interal os (see figure below). The images below are taken with the probe placed sagitally in the lower uterine segment.



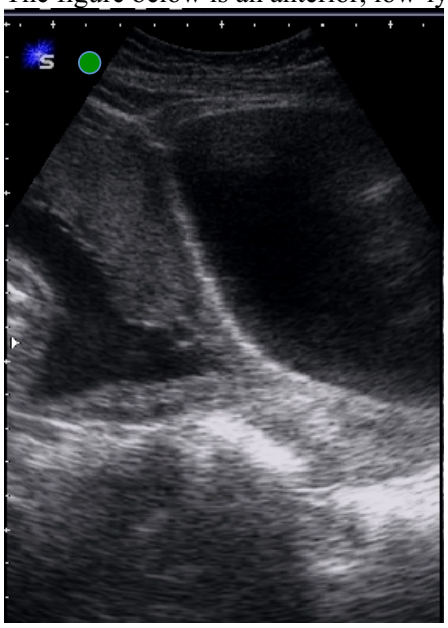
Partial placenta previa (type III), will be partially covering the internal os, while marginal placenta previa (type II) will be bordering the internal os.

Marginal placenta previa (grade II) will be bordering the internal os (see figure below).



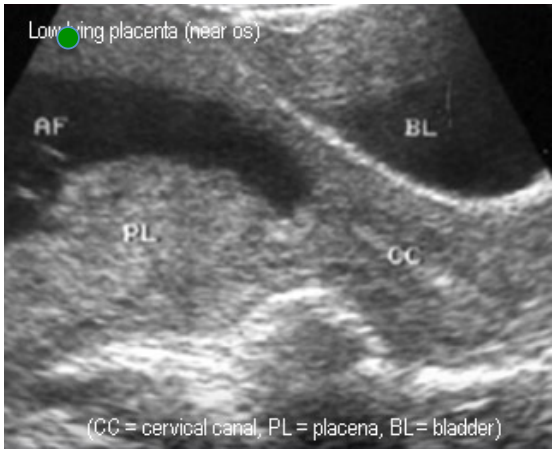
A low-lying placenta (type I) will be near, but not touching the internal os (usually 2cm or less from the os).

The figure below is an anterior, low-lying placenta.



*This image is an example with a full bladder. Full bladders may make placentas look low-lying when they are not.

The figure below is a posterior, low-lying placenta.



Consent form

NCP Ultrasound Study Consent Form

GREETING AND PURPOSE
Namaste! I am with NNIPS. We have worked in your community for 25 years, and you are enrolled in our study of oil massage of babies. I'd like to talk to you about a new project. We are doing a new study to learn if ANMs (like me) can do exams for pregnant women (like you) soon before they deliver their baby. We will use a portable ultrasound machine to check the position of your baby, the placenta, and if you are having twins. In this study, we will save pictures and send them to a doctor in Kathmandu. The doctor will help us learn if the other ANMs and I are doing a good job checking these three issues.

PROCEDURES
If you agree, we will do the exam here in your home using this machine, which helps me see your baby. Both of us will do the exam, one at a time. First we will find a private place here where you can lie down for the exam. To do the exam, you will need to remove your clothes just enough so your belly is showing. Then, we will put some special gel on your belly, which will help the machine see your baby. This part of the machine, which is like a camera, will touch the skin of your belly. We will then click this button to take a picture. It will take about 15 minutes for each of us to do this exam, and we will show you a picture at the end.

RISKS/DISCOMFORTS
This machine does not put you or your baby at risk. We will do the exam privately. We will wash our hands with soap before the exam. The gel might feel a bit cold when we put it on your belly.

BENEFITS
We might find a possible problem with your pregnancy when doing the exam. If we do, we will tell you and advise you to go to a health center or hospital to get care. If we see a problem with the location of your placenta, we will send the picture to the Kathmandu doctor to ask for his/her advice, and then come back to your house a week later to notify you of what we find. If you like, we can also tell your husband and others who help care for you in your pregnancy.

We have only received basic training in using ultrasound. We have only been taught to examine the position of the baby and placenta and if you are having twins, but not other problems. However, if we have concerns, we will let you know We advise all pregnant women to have regular checkups at a facility, and if possible, everyone should deliver at a birthing center. We cannot see if your baby is a boy or girl.

CONFIDENTIALITY / VOLUNTARINESS
We will keep your information private and not share it with anyone else. We keep our forms locked up when staff are not viewing them. The picture of your baby will not have your name on it, only a study number. We will only use this study number for this study. You can choose to be in this study or not. If you agree, you can stop anytime. If you don't want to be in this study, that is ok, and it will not affect your access to health care or NNIPS activities now or in the future.

PERSON TO CONTACT
If you have any questions or problems about the study, I can answer them now or you can contact the Project Director, Dr. Subarna Khatry at NNIPS office in Hariaun, Sarlahi (phone no. 046-530135)

PERMISSION TO PROCEED Is it okay to proceed with today's activities?

Forms

Nepal Oil Massage Study – NCP ANM Ultrasound Assessment Form

Week ☐☐☐ **Date** ☐☐-☐☐-☐☐ **Worker ID** ☐☐☐ _____

VDC ☐☐ **Ward** ☐ **Sector** ☐ **HH** ☐☐☐

Woman's NNIPSNUM ☐☐☐☐☐☐ **First Names** _____ **Last Name** _____

Examining 1st or 2nd? ☐ 1=first (do consent) 2=second **Consented?** ☐ 1=Yes 6=No **(STOP)** **Start time of exam** ☐☐ **HH** ☐☐ **MM**

1. Multiple pregnancy?	☐ 0 = No 1 = Yes
2.Non-cephalic presentation?	Baby 1 / Twin A ☐ Twin B ☐ 1=cephalic 2=breech 3=transverse 4=oblique
3. Fetal heartbeat?	Baby 1 / Twin A ☐ Twin B ☐ 0 = No heartbeat detected 1 = Heartbeat detected
4. Placental position?	☐ 1 = Anterior (mother's front) 2 = Posterior (mother's back) 3 = Right lateral 4 = Left lateral 5 = Superior / fundal (mother's head side) 6 = Placenta previa / low-lying placenta (go to Q4a) 9 = cannot determine
4a. Placenta previa status	☐ 1 = low-lying, marginal, or partial previa 2 = complete previa 9 = cannot determine
Notes: _____ _____	
Exam completed? ☐	0=No (record reason below) _____ _____ 1=Yes **If Y, # of images taken** ☐

Nepal Oil Massage Study – NCP Ultrasound Eligibility List

VDC # # VDC NAME

NNIPS Week for which report was created ###

W	S	HH	Woman's NNIPSNUM	Woman's Name	Husband's Name	Status
#	#	###	######	Woman's name	Husband's name	☐ _____

1 = Met and examined
2 = Not Met (write reason)
3 = Already delivered
4 = Already examined
6= Refused

EVERYTHING IN RED IS WHAT THE KTM DATA CENTER SHOULD FILL OUT.

This list is being requested to identify all mothers who are gestational age ≥32 weeks on a specified NNIPS week in a specified VDC. The Ultrasound Study team will provide the VDC number and the NNIPS week.

The rule of eligibility is as follows:
(The date of the Monday of the NNIPS week the report is being requested for – LMP date) / 7 ≥ 32.

Please list all eligible women, sorted by Ward – Sector – Household - NNIPSNUM. There is no need to report their gestational age.

Nepal Oil Massage Study – NCP Ultrasound Rapid Assessment Log

Week ☐☐☐ Visit date ☐☐-☐☐-☐☐ Staff ID ☐☐☐

VDC ☐☐ W ☐ S ☐ HH ☐☐☐

NNIPSNUM ☐☐☐☐☐☐ Mother's first names _____ Last name _____

Reason ☐

1 = suspected placenta previa
2 = suspected abnormality

_____

_____

_____

SMS sent? (Y/N) ☐ Images sent? (Y/N) ☐

Response from IOM:

_____

_____

_____

a) If placenta previa check, visit made (Y/N)? ☐ Revisit date ☐☐-☐☐-☐☐

b) If abnormality check, abnormality diagnosed by IOM (Y/N)? ☐ If Y, visit made? (Y/N) ☐ Revisit date ☐☐-☐☐-☐☐

Job aides

NOMS NCP Ultrasound Substudy - Image Capture and Labeling Protocol

Multiple pregnancy

0) Image with both twins
   a. Twin A (closer to the cervix)
   b. Twin B (farther from the cervix)

Fetal presentation

1) Image of baby's body
   a. Sagittal (SAG) or transverse (TRV)

*If twins, take one image for each twin (label one image as twin A, label one image as twin B).

Fetal heartbeat

No image.

Placental location

2) Sagittal image of the placenta, including the lower margin if possible.
   a. Sagittal (SAG)
   b. Right lateral, midline, or left lateral (RT, ML, LT)
   c. Placenta (PL)

3) Transverse image of the placenta.
   a. Transverse (TRV)
   b. Superior, middle, or inferior (SUP, MID, INF)
   c. Placenta (PL)

Confirm placenta previa and fetal presentation

4) Sagittal image of the internal os/cervix and try to capture the lower margin of the placenta.
   a. Sagittal (SAG)
   b. Lower uterine segment (LUS)
   c. Cervix (CX).

*If the placenta is low, take a measurement with calipers.

*If you have a unique case like a mother with two placentas, just take an image of one placenta and write about the unique situation in the notes section.
*If abnormalities are seen, take extra images after you finish taking all required images.

NOMS NCP Ultrasound Substudy – Home Visit Protocol

1) Visit the home. Write the status on the NCP Ultrasound Eligibility List.

2) Consent the mother.

3) Secure privacy for the mother. Allow mother to decide who can watch the exam (up to two people).

4) Set up the machine and the probe/gel stand.

5) 1st ANM conduct the exam. Review the images and fill out the NCP ANM Ultrasound Assessment Form. When finished, open the "new patient" screen for the next ANM.

6) 2nd ANM conduct the exam. Review the images and fill out the NCP ANM Ultrasound Assessment Form. When finished, show image of the fetus to the mother. Then open the "new patient" screen for the next exam.

7) Clean the probe and carefully pack the machine.

8) ANMs decide together which referral message to give based on their diagnoses.

9) Give the appropriate referral message. Allow the mother to decide who in her family should also hear the referral message.

- If nothing is suspected, give the appropriate referral message.

- If multiple gestation or non-cephalic presentation is suspected, give the appropriate referral message and the Referral Facilities List.

- If placenta previa is suspected, give the appropriate referral message and the Referral Facilities List and fill out the NCP Ultrasound Rapid Assessment Log.

- If an abnormality is suspected, give the same message as "nothing suspected," and fill out the NCP Ultrasound Rapid Assessment Log.

Referral forms

Facilities with cesarean section services available

Government (no cost for delivery, ama surakcha karyakaram will also provide 500 rupees)
Janakpur Anchal Hospital, Janakpur
Narayani Anchal Hospital, Birganj
Hetauda Hospital, Makwanpur
Bharatpur Hospital, Chitwan

Private (please note that this is not a complete list)
Dhanusha Nursing Home, Janakpur (must pay for delivery)
Janaki Health Research Center, Janakpur (must pay for delivery)
National Medical College Teaching Hospital, Birganj (no cost for delivery)
Advance Nursing Home, Birganj (must pay for delivery)
Narayani Samudayik, Bharatpur (must pay for delivery)
Chitwan Medical College, Chitwan (no cost for delivery)

Suggested birthing centers (no cesarean section available, no cost for delivery, ama surakcha karyakaram will also provide 500 rupees)

Haripur Primary Health Center
Lalbandi Primary Health Center
Malangawa District Hospital
Pariwar Niyojan Sastha (FPAN), Hariaun

Patient name:

Patient address:

Date examined:

There is high suspicion of placenta previa. An exam to confirm the diagnosis should be conducted at a referral facility.

Dr. Ram Kumar Ghimire
Dr. Sharma Paudel
Balposhan Yojana, Sarlahi

Referral script

NCP Ultrasound Study – Referral Script

Script if no issues detected by ANMs

Our exam shows that your baby is in the right position and that the placenta is in the correct position. However, conditions may change, an ultrasound exam may not find all problems, and we are not trained to find all problems using the ultrasound machine. Unexpected problems can occur during labor and delivery. Giving birth at a birthing center will better ensure your health and your baby's health. You and your family should have a plan for emergency transportation to seek care at an appropriate facility and for ways to pay for emergency expenses in case a problem occurs.

Script if issues detected by ANM(s)
Instruction: Read the relevant script, depending on which problem was detected by the ANM(s).

If non-cephalic presentation:
Your baby may not be positioned with its head down. When the baby is not head down at the time of delivery, the baby could get stuck, which could cause the mother and baby harm. We highly suggest that you deliver the baby at a facility that has the ability to conduct a cesarean section operation so it is available if you need it. We will provide you a list of the closest facilities that are able to conduct cesarean section. In case you are not able to go to those facilities, we will also provide a list of birthing centers that has trained staff who can do uncomplicated deliveries of babies who are not positioned head down.

Because we have only received basic training with this machine, it is possible that there are no problems with your baby's position. Also, about half of the babies who are positioned with the head up late in pregnancy will turn around before the time of delivery. Even if the baby turns around, unexpected problems can occur during labor and delivery. An ultrasound exam may not find all problems. We are also not trained to find all problems using the ultrasound machine. Giving birth at a birthing center will better ensure your health and your baby's health. You and your family should have a plan for emergency transportation to seek care at an appropriate facility and for ways to pay for emergency expenses in case a problem occurs.

If multiples:
It looks like you are having two babies. Mothers of twins have a higher chance of having a hard time during delivery, and the mother and babies may be harmed. We highly suggest that you deliver the baby at a facility that has the ability to conduct a cesarean section operation so it is available if you need it. We will provide you a list of the closest facilities that are able to conduct cesarean section. In case you are not able to go to those facilities, we will also provide a list of birthing centers that has trained staff who can do uncomplicated deliveries of twins.

Because we have only received basic training with this machine, it is possible that you are only pregnant with one baby. Even if you are only pregnant with one baby, unexpected problems can occur during labor and deliver. An ultrasound exam may not find all problems. We are also not trained to find all problems using the ultrasound machine. Giving birth at a birthing center will better ensure your health and your baby's health. You and your family should have a plan for emergency transportation to seek care at an appropriate facility and for ways to pay for emergency expenses in case a problem occurs.

If placenta previa:
Your placenta might be in a position that can cause a problem during labor and delivery. Babies and mothers with the placenta in the wrong location may have a hard time during delivery, and may be harmed through problems like heavy bleeding. We will send the images we have taken today to a doctor in Kathmandu, and we will return to your house within the next week to tell you what the doctor found. In the

meantime, if you have vaginal bleeding, it is important for you to go to a birthing center to be checked, as it may be a sign that your placenta is in the wrong location. We will provide you with names of facilities that can handle a problem like this one.

At follow-up visit:
If placenta previa not detected: We have found that the placenta is currently in the correct position. However, conditions may change. An ultrasound exam may not find all problems. We are also not trained to find all problems using the ultrasound machine. We recommend that you deliver at a birthing center to reduce any problems during labor and delivery. Unexpected problems can occur during labor and delivery, and giving birth at a birthing center will better ensure your health and your baby's health. You and your family should have a plan for emergency transportation to seek care at an appropriate facility and for ways to pay for emergency expenses in case a problem occurs.

If placenta previa detected – same message to be delivered independently to pregnant woman/mother/mother-in-law and husband.

We have found that the placenta is currently in a location that is likely to cause problems during the rest of your pregnancy. Without proper care, you may experience problems like a lot of bleeding during delivery and even death of the baby or the mother. Between now and your delivery, we suggest that you avoid all hard physical activity and rest lying down as much as possible until the baby arrives. Sex must be avoided for the rest of pregnancy. If you experience vaginal bleeding at anytime, it is very important for you to go to a birthing center to be checked.

In most situations when the placenta is located low on a pregnant woman's body, an operation is needed to deliver the baby, as the baby will not be able to come out properly. We highly suggest that you deliver the baby at a facility that has the ability to conduct a cesarean section operation so it is available if you need it. We will provide you a list of the closest facilities that are able to conduct cesarean section. It is possible that the position of your placenta will not cause any problems but unexpected problems can occur during labor and delivery, and giving birth at a facility with the ability to conduct cesarean section will better ensure your health and your baby's health. You and your family should have a plan for emergency transportation to seek care at an appropriate facility and for ways to pay for emergency expenses in case a problem occurs.

If fetal heartbeat not detected or other problem on ultrasound:

We think that there may be something abnormal with the health of your baby. As we cannot be sure, we strongly urge you to visit the nearest birthing center immediately for further check-up. We will provide you with names of these facilities.

We recommend that you deliver at a birthing center to reduce any problems during labor and delivery. Unexpected problems can occur during labor and delivery, and giving birth at a birthing center will better ensure your health and your baby's health. You and your family should have a plan for emergency transportation to seek care at an appropriate facility and for ways to pay for emergency expenses in case a problem occurs.

In-depth interview

FEMALE FAMILY MEMBER'S IN-DEPTH INTERVIEW CONSENT

In-depth interview consent form – Female Family Member

GREETING AND PURPOSE
Namaste! I am with NNIPS. We have worked in your community for 25 years, and your daughter-in-law is enrolled in our study of oil massage of babies. I'd like to talk to you about a new project.

We are doing this new study to learn more about how best to care for babies who are delivered in a position other than its head first. We have identified mothers who recently had a baby delivered without its head first, and we are asking the [mother-in-law/mom/sister/sister-in-law] who helped making decisions on care during labor and delivery to participate. We would like to ask you questions related to the position of the baby, how people in your community think about the position of the baby at delivery, and your own experience with your [daughter-in-law/daughter/sister/sister-in-law]'s most recent pregnancy.

PROCEDURES
We will ask you to find a private place in your house for us to ask you some questions. There will be one interviewer. We will record the conversation, so that we can remember everything that we talk about. We will ask you questions about your experiences and thoughts about the position of the baby when it was delivered. The interview will last no longer than one hour.

RISKS/DISCOMFORTS
There are no significant risks to you if you take part in this study. If there is a question you don't want to answer, we can move on to something else. Also, if you want me to pause the recording, just tell me. We can end the discussion at any time, if you want.

BENEFITS
There are no direct benefits to you from being in our study. Our findings from this interview may help improve care for babies who are delivered in a position other than head first.

CONFIDENTIALITY / VOLUNTARINESS
Your answers will not be shared outside of the NNIPS project, and will only be used for this research study. Your answers to our questions and the audio recording will be locked in cabinets at the NNIPS offices. You have a choice to participate in this study and you may say yes or no. If you agree now, you can change your mind and withdraw from the study at any time. If you don't want to participate, that is ok; it will not affect your access to health care or NNIPS activities now or in the future.

PERSON TO CONTACT
If you have any questions or problems about the study, I can answer them now or you can contact the Project Director, Dr. Subarna Khatry tat NNIPS office in Hariaun, Sarlahi (phone no. 046-530135)

PERMISSION TO PROCEED
Is it okay to proceed with today's activities?

WOMAN'S IN-DEPTH INTERVIEW CONSENT

In-depth interview consent form – Woman

GREETING AND PURPOSE
Namaste! I am with NNIPS. We have worked in your community for 25 years, and you are enrolled in our study of oil massage of babies. I'd like to talk to you about a new project. We are doing this new study to learn more about how best to care for babies who are delivered in a position other than its head first. We are asking mothers who had a baby delivered without its head coming out first to participate. We would like to ask you questions related to the position of the baby, how people in your community think about the position of the baby at delivery, and your own experience with your most recent pregnancy.

PROCEDURES
We will ask you to find a private place in your house for us to ask you some questions. There will be one interviewer. We will record the conversation, so that we can remember everything that we talk about. We will ask you questions about your experiences and thoughts about the position of the baby when it was delivered. The interview will last no longer than one hour.

RISKS/DISCOMFORTS
There are no significant risks to you if you take part in this study. If there is a question you don't want to answer, we can move on to something else. Also, if you want me to pause the recording, just tell me. We can end the discussion at any time, if you want.

BENEFITS
There are no direct benefits to you from being in our study. Our findings from this interview may help improve care for babies who are delivered in a position other than head first.

CONFIDENTIALITY / VOLUNTARINESS
Your answers will not be shared outside of the NNIPS project, and will only be used for this research study. Your answers to our questions and the audio recording will be locked in cabinets at the NNIPS offices. You have a choice to participate in this study and you may say yes or no. If you agree now, you can change your mind and withdraw from the study at any time. If you don't want to participate, that is ok; it will not affect your access to health care or NNIPS activities now or in the future.

PERSON TO CONTACT
If you have any questions or problems about the study, I can answer them now or you can contact the Project Director, Dr. Subarna Khatry at NNIPS office in Hariaun, Sarlahi (phone no. 046-530135)

PERMISSION TO PROCEED Is it okay to proceed with today's activities?

NCP Qualitative Study – IDI Interview Guide, Female Family Member

We are interviewing family members of women who had a baby who was delivered upside down, and we are trying to understand how to best care for mothers and babies who have these experiences. Thank you for agreeing to do the interview.

We will start the interview now. I am turning on the recorder.

BACKGROUND
Let's start with telling me a little about yourself.
How old are you?
Who is in your family?
How many children do you have?
How old were you when you had your first child?

PREGNANCY
Now, I want to ask you questions that are about your [daughter-in-law, daughter, sister-in-law, sister's] most recent pregnancy.

Can you tell me a little about her most recent pregnancy?

DURING LABOR AND DELIVERY

1) Can you tell me about what happened during labor and delivery?
   ---PRB---Can you tell me more about this / the problems that happened?
   ---PRB--- Can you tell me what you did to handle the problems that happened during labor and delivery?
   ---PRB---What roles did your family members play during labor and delivery?
2) If you know, what part of the baby came out first?
3) Can you tell me about if the baby coming upside down affected her delivery?
   ---PRB--- Can you tell me about the condition of the baby after delivery?
   FOR ALIVE BABIES ---PRB---Can you tell me about the condition of the baby now?
   FOR DEAD BABIES ---PRB---Can you tell me a little about what the reasons you think that the baby died / was born dead?
4) Where did you want your [daughter-in-law, daughter, sister-in-law, sister] to deliver the baby?
5) How did you decide to deliver at [home / facility]?
6) How did you decide not to deliver at [home / facility]?

BEFORE LABOR AND DELIVERY

1) Did you know that her baby was upside down before delivery?
   ---PRB--- If yes, how did you find out?
---PRB---Did you do anything after you found out that the baby is upside down?
2) Can you tell me about any problems she experienced during the pregnancy?
   ---PRB--- How were the problems handled?
3) Is there anything else you would like to tell me about the time of pregnancy?
   ---PRB--- How about care she received from family, traditional healers, or health facility?

UPSIDE DOWN BABIES
1) Has she had any previous pregnancies when the baby was delivered upside down?

---PRB---If so, can you tell me a little about that experience?
---PRB---Did you know that her baby was upside down before delivery?
---PRB---If yes, how did you find out?
---PRB---Did you do anything after you found out that the baby is upside down?
---PRB---If you know, what part of the baby came out first?
---PRB--- Can you tell me about if the baby coming upside down affected her delivery?

2) Sometimes babies are born upside down. What did you know about babies that are born upside down before the delivery of this upside down baby?
---PRB--- What can be done if the child is upside down?
---PRB---What can be done during delivery for a child that is upside down?

3) Have you heard of any causes to babies being born upside down?

CONCLUSION
Do you have anything else you would like to add to the interview before we finish?
Thank you so much for your time. I am now turning off the recorder and we are now finished with the interview.

NCP Qualitative Study – IDI Interview Guide, Woman

We are interviewing women who had a baby who was delivered upside down, and we are trying to understand how to best care for mothers and babies who have these experiences. Thank you for agreeing to do the interview.

We will start the interview now. I am turning on the recorder.

BACKGROUND
Let's start with telling me a little about yourself.
How old are you?
Who is in your family?
How many children do you have?
How old were you when you had your first child?

PREGNANCY
Now, I want to ask you questions that are about your most recent pregnancy.

Can you tell me a little about your most recent pregnancy?

DURING LABOR AND DELIVERY
1) Can you tell me about what happened during labor and delivery?
---PRB---Can you tell me more about this / the problems that happened?
---PRB--- Can you tell me what you did to handle the problems that happened during labor and delivery?
---PRB---What roles did your family members play during labor and delivery?
2) If you know, what part of the baby came out first?
3) Can you tell me about if the baby coming upside down affected your delivery?
---PRB--- Can you tell me about the condition of your baby after delivery?
FOR ALIVE BABIES ---PRB---Can you tell me about the condition of the baby now?
FOR DEAD BABIES ---PRB---Can you tell me a little about what the reasons you think that your baby died / was born dead?
4) Where did you want to deliver the baby?
5) How did you decide to deliver at home / facility?
6) How did you decide not to deliver at home / facility?

BEFORE LABOR AND DELIVERY

1) Did you know that your baby was upside down before delivery?
---PRB--- If yes, how did you find out?
---PRB---Did you do anything after you found out that the baby is upside down?
2) Can you tell me about any problems you experienced during the pregnancy?
---PRB--- How were the problems handled?
3) Is there anything else you would like to tell me about the time of pregnancy?
---PRB--- How about care she received from family, traditional healers, or health facility?

UPSIDE DOWN BABIES
1) Have you had any previous pregnancies when the baby was delivered upside down?
---PRB---If so, can you tell me a little about that experience?
---PRB---Did you know that your baby was upside down before delivery?

---PRB---If yes, how did you find out?
---PRB---Did you do anything after you found out that the baby is upside down?
---PRB---If you know, what part of the baby came out first?
---PRB--- Can you tell me about if the baby coming upside down affected your delivery?

2) Sometimes babies are born upside down. What did you know about babies that are born upside down before the delivery of this upside down baby?
---PRB--- What can be done if the child is upside down?
---PRB---What can be done during delivery for a child that is upside down?

3) Have you heard of any causes to babies being born upside down?

CONCLUSION
Do you have anything else you would like to add to the interview before we finish?
Thank you so much for your time. I am now turning off the recorder and we are now finished with the interview.

Forms

Interview # ☐ Circle one each: Home / Facility delivery; Baby Alive / Died

Notes:

Non-cephalic Presentation – In-depth Interview Form

VDC ☐☐ Ward ☐ Sector ☐ HH ☐☐☐

Woman's NNIPSNUM ☐☐☐☐☐☐ Woman's Name _____ Husband's name _____

Worker ID ☐☐☐ _____ Date ☐☐-☐☐-☐☐

Who are you interviewing? ☐
1 = woman
2 = mother-in-law
3 = other _____
4 = could not find person to interview

Consented? ☐ 1=Yes 6=No (STOP)

Recorder number ☐

Interview Summary – please include ***at least*** the following: 1) experience during labor and delivery, 2) whether they knew baby was upside down before labor, 3) what care they sought specific to baby being upside down, 4) their perceptions toward upside down babies.

More on back? ☐

Interview # ☐

Description of home / interview environment:

Description of person you interviewed:

More on back? ☐

Interview # ☐

Other:

Summary of background section in interview:

More on back? ☐

Focus group materials

Consent form

NCP Study – Focus Group consent form

GREETING AND PURPOSE
Namaste! I am with NNIPS. We have been working in your community for the past 25 years. I would like to tell you more about this project, ask for your consent to take part in it, and answer questions you may have. We are doing a new study to learn more about caregiving and care-seeking during pregnancy, labor, and delivery. To understand more about this, we are bringing members of your community together to talk about this.

PROCEDURES
We are inviting people in this community to participate in a group discussion. The discussion will have about 6-8 people, and will also include a researcher who will guide the discussion and a note taker. We will audio record and describe the rules for the discussion. Everyone will be given a card with a number to place in front of them. We will use this number instead of your name in the notes that we write down about this discussion. In the discussion, you will be asked questions about your understanding of what could lead to bad outcomes in pregnancy for the new baby or the mother, when and how they decide to seek care, and from whom or where they seek care. The discussion will take about an hour.

RISKS/DISCOMFORTS
There are no significant risks to you for taking part in this study. The other community members in your discussion group will know your responses to the questions asked. You will be asked to respect the privacy of the people in their group by not sharing what was talked about after it is over or with anyone not in the group. You will not be asked to talk about any personal experiences—only how your community feels about the topics being discussed. We will have this discussion in a private place. You can choose not to answer any question you don't want to answer.

BENEFITS
There are no direct benefits to you from participating in our study. We hope that our findings from the discussion will help improve pregnancy outcomes for women in your community.

CONFIDENTIALITY/VOLUNTARINESS
Information that you give will stay with NNIPS and not be shared with anyone else. Your name or address will not be collected, and any notes or the audio recording will be kept in locked cabinets and computers at our NNIPS offices. The information you provide will only be used for this research study. You have a choice to participate in this study and you may say yes or no. If you do agree to participate, you can change your mind and withdraw from the study at any time. If you do not agree to participate, it will not affect your access to health care or NNIPS activities now or in the future.

PERSON TO CONTACT
If you have any questions or problems about the study, I can answer them now or you can contact the Project Director, Dr. Subarna Khatry tat NNIPS office in Hariaun, Sarlahi (phone no. 046-530135)

PERMISSION TO PROCEED
Is it okay to proceed with today's activities?

Focus group guide

NCP Qualitative Study – Focus Group Guide

General pregnancy care

Today we are going to ask you questions about problems women in your community experience during pregnancy and how they are handled.

1) What are some things that are done for a pregnant woman to make sure she and the baby are healthy during pregnancy?

2) What are some things during pregnancy that suggest that the pregnant woman or the baby may have health problems?

---PRB--- How about during labor and delivery?
---PRB--- How about before labor and delivery?

3) How does one deal with those issues?

Fetal presentation

Sometimes babies are born upside down. We are now going to ask you some questions about that.

1) What do you know about babies that are born upside down?
2) How can one tell prior to delivery that a baby is coming out upside down?
3) What can be done if the child is upside down?
4) What are some concerns regarding babies who are upside down?
5) What can be done during delivery for a child that is upside down?
6) Do you know any friends or neighbors who had a baby born upside down?
---PRB--- What was their experience like?
7) What causes babies to come out upside down?
8) Do you have anything else to add about upside down babies?

Delivery preferences

Some people in your community choose to deliver a baby at home. Some people choose to deliver a baby at a facility.

What are some reasons women prefer home deliveries?
What are some reasons women prefer facility deliveries?

What do people in your community think about cesarean section operations?

Conclusion

Is there anything else you would like to say before we finish?
Thank you so much for your time today.

Forms

NCP Focus Group Form – **Mother's Group**

Date ☐☐-☐☐-☐☐ VDC ☐☐ _____

Focus group # ☐ Facilitator worker ID ☐☐☐ Notetaker worker ID ☐☐☐

Participant	Consented? (Y/N)	Age	Number of children (Must be at least 2)	Age of youngest child (Must be less than 5)	Consented by (write worker ID)
1					
2					
3					
4					
5					
6					
7					
8					

Please describe the location the focus group was conducted.

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Yoshida, S., Rudan, I., Lawn, J. E., Wall, S., Souza, J. P., Martines, J., . . . neonatal health research priority setting, g. (2014). Newborn health research priorities beyond 2015. *Lancet, 384*(9938), e27-29. doi:10.1016/S0140-6736(14)60263-4

Zou, G. (2004). A modified poisson regression approach to prospective studies with binary data. *Am J Epidemiol, 159*(7), 702-706. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/15033648

Curriculum Vitae

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EDUCATION

PhD, Department of International Health Dec 2015
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
Concentration: Global Disease Epidemiology and Control; Reproductive, Maternal, Neonatal, and Child Health

- *Grant written and won*: Cappsci Data for Life, grant title: "Testing the feasibility of portable ultrasound exams to reduce intrapartum-related fetal and neonatal death"
- *Awards:*
  - Four-year merit-based tuition and stipend support from the Department of International Health
  - David and Elinor Bodian Scholarship, 2015
  - Procter and Gamble Fellowship, 2014
  - Delta Omega Scholarship, 2014
  - Baker, Reinke, Taylor Scholarship in International Health, 2014
  - International Health Alumni Award, 2013

Master of Science in Public Health, Department of International Health May 2011
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD
Concentration: Global Disease Epidemiology and Control

- Delta Omega public health honors society inductee

Bachelor of Arts, Political Science and International Studies May 2006
Yale University, New Haven, CT

RESEARCH EXPERIENCE

Doctoral Student Investigator Feb 2014 – Dec 2015
Nepal Nutrition Intervention Project – Sarlahi; Sarlahi, Nepal

- Designed and implemented a validation study on the diagnostic accuracy of lower-level health workers diagnosing obstetric risk factors for intrapartum-related complications via home-based ultrasound exams, coordinated collaboration with Johns Hopkins Hospital and Tribhuvan University Teaching Hospital for ultrasound training and gold standard evaluation of sonograms
- Designed and implemented a prospective cohort study on obstetric risk factors and their associations with pregnancy complications, developed and piloted relevant data collection forms
- Coordinated in-depth interviews and focus groups for study on perceptions of and care-seeking related to non-cephalic presentation, conducted training for and supervised local staff on qualitative research methods
- Surveyed local health facilities regarding standard of care for obstetric risk factors such as non-cephalic presentation and multiple gestation

- Conducted data quality control, data cleaning, and analysis for large community-based research trials

Research Associate - Child Health Epidemiology Reference Group Mar 2010 – Dec 2015
Johns Hopkins Bloomberg School of Public Health**,** Baltimore, MD
- Served as the primary data analyst and author on manuscripts on small-for-gestational-age (SGA) births and the following risk factors: 1) reproductive health risk factors (maternal parity, age, and birth spacing), 2) chronic maternal nutrition as represented by short maternal stature, 3) maternal anemia
- Conducted systematic reviews and analyses on major neonatal morbidities (neonatal encephalopathy, neonatal infections)
- Conducted research and analyses on neonatal and infant mortality risk associated with and the percent of mortality attributable to SGA births
- Coordinated data sharing and analyses from 15 research groups

Research Assistant – Child mortality inequity project Oct 2012 – Feb 2013
Johns Hopkins Bloomberg School of Public Health**,** Baltimore, MD
- Conducted data analysis on DHS datasets, examining national-level under-5 mortality gaps across socioeconomic strata, and calculating expected global mortality reduction if gaps in within-country under-5 mortality rates were to be reduced

Masters Student Investigator Jul – Dec 2010
Nepal Nutrition Intervention Project – Sarlahi, Sarlahi, Nepal
- Implemented and monitored the roll-out of a large randomized community-based trial on newborn oil massage study and trained and supervised staff on data collection, human subjects research, and anthropometric measurements, and validated tools
- Coordinated cookstove installation for a randomized cookstove replacement study by drafting procedures, training staff, and implementing and supervising installation in the field
- Created new pregnancy care pamphlet for distribution to research participants

Research Assistant – Maternal social support and vaccine timeliness of children
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD Mar - Jun 2010
- Conducted data analysis to determine association between social support/depression indicators for mothers and timeliness of their children's vaccinations in rural Brazil

PROGRAMMATIC EXPERIENCE

Monitoring and Evaluation Consultant Jun 2011- present
Save the Children, Saving Newborn Lives Initiative, Washington, DC
- Launched pilot project on community-based follow-up of low birth weight babies discharged from facilities (Dowa District, Malawi)
- Developed data dissemination procedure and evaluation protocol for a qualitative study examining barriers and facilitators of Health Surveillance Assistants' (government-sponsored community health workers) performance in maternal and newborn health-related activities (Thyolo District, Malawi)
- Revised supervisory and evaluation procedures for a community-based maternal and newborn care project in three districts (Malawi)
- Published systematic review on community-based newborn referral completion rates

- With Water, Sanitation, and Hygiene (WASH) Program: Composed report on existing evidence linking WASH interventions and maternal, neonatal, and child health, highlighted gaps in research

Research Assistant - Helping Babies Breathe evaluation project Oct 2012- Dec 2013
Maternal and Child Health Integrated Program, John Hopkins Bloomberg School of Public Health, Baltimore, MD

- Conducted an evaluation on a facility-based birth asyphxia prevention program, using facility-level observational data on newborn and asphyxia-related care practices and equipment in Malawi
- Analyzed and compiled data on quality of care related to labor and delivery in Malawian facilities

TEACHING EXPERIENCE

Teaching Assistant
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

- Introduction to International Health (Sep – Oct 2015)
- Doctoral Seminar in International Health (Sep – Dec 2013)
- Design and Conduct of Community Trials (Jan – Mar 2011)

Yale-China Teaching Fellow Jun 2007 - Jun 2009
Yali Senior High School, Yale-China Association Teaching Fellowship, Changsha, China

- Developed a year-long curriculum focusing on conversational English skills, participation, and creative thinking, instructed high school sophomores and juniors in conversational English

PUBLICATIONS

Peer-reviewed articles

Kozuki N, Katz J, Lee AC, Vogel JP, Silveira M, Sania A, Stevens G, Caulfield LE, et al. Short maternal stature as risk factor for small-for-gestational-age and preterm birth in low-and middle-income countries: meta-analysis and population attributable risk. Journal of Nutrition. 2015 Sep.

Kozuki N, Guenther T, Vaz L, Moran A, Soofi SB, Nalwadda C, Peterson SS, Bhutta ZA, Khanal S, Tielsch JM, Doherty T, Nsibande D, Lawn JE, Wall S. A systematic review of community-to-facility neonatal referral completion rates in Africa and Asia. BMC Public Health. 2015 Sep, 15:989.

Kozuki N, Katz J, Christian P, Lee AC, Liu L, Baqui AH, Humphrey J, Huybregts L, et al. Prevalence and mortality risk of small-for-gestational-age using the INTERGROWTH-21st birthweight standard. JAMA-Peds. 2015 July, 169(7): e151438.

Lee AC, Chandran A, Herbert HK, **Kozuki N,** Markell P, Shah MR, Campbell H, Rudan I, Baqui AH. Treatment of infections in young infants in low- and middle-income countries: a systematic review and meta-analysis of frontline health worker diagnosis and antibiotic access. PLoS Med. 2014 Oct, 14:11(10).

Kozuki N, Katz J, LeClerq S, Khatry SK, West KP, Christian P. Risk factors and neonatal/infant mortality risk of small-for-gestational-age and preterm birth in rural Nepal. Journal of Maternal-Feteal and Neonatal Medicine. 2014 July, e-version.

Katz J, Wu LA, Mullany LC, Coles CL, Lee AC, **Kozuki N,** Tielsch JM. Prevalence of small-for-gestational-age and its mortality risk varies by choice of birthweight-for-gestation reference population. PLoS ONE. 2014 March, 9(3): e92074.

Amouzou A, **Kozuki N,** Gawtkin DR. Estimation of the contribution of disparities within developing countries to global inequalities in under-five mortality. BMC Public Health. 2014 March, 14:216.

Lee AC, **Kozuki N**, Blencowe H, Bahalim A, Vos T, Darmstadt G, Cousens S, Lawn J. Intrapartum-related neonatal encephalopathy incidence and impairment at a regional and global level for 2010 and trends from 1990. Pediatric Research. 2013 December, 74, 50-52.

Kozuki N, Lee AC, Silveira M, Sania A, Vogel J, Adair L, Barros F, Caulfield, L, et al. The Association of Parity and Maternal Age with Small-for-Gestational-Age, Preterm, and Neonatal and Infant Mortality: A Meta-analysis. BMC Public Health. 2013 September, 13(Suppl 3): S2.

Kozuki N, Lee AC, Silveira M, Victora C, Adair L, Humphrey J, Ntozini R., Black R, Katz J. The Associations of Birth Intervals with Small-for-Gestational-Age, Preterm, and Newborn and Infant Mortality: A Meta-Analysis. BMC Public Health. 2013 September, 13(Suppl 3): S3.

Kozuki N, Sonneveldt E, Walker, N. Residual confounding explains the association between high parity and child mortality. BMC Public Health. 2013 September, 13(Suppl 3): S5.

Kozuki N, Walker N. Exploring the association between short/long preceding birth intervals and child mortality: using reference birth interval children of the same mother as comparison. BMC Public Health. 2013 September, 13(Suppl 3): S6.

Lee AC, Katz J, Blencowe H, Cousens S, **Kozuki N**, Vogel J, Adair L. et al. National and regional estimates of term and preterm babies born small-for-gestational-age in 138 low-income and middle-income countries in 2010. Lancet Global Health. 2013 July, 1(1), e26-236.

Katz J, Lee AC, **Kozuki N**, Lawn J, Cousens S, Blencowe H, Ezzati M, Bhutta Z, et al. Mortality risk in preterm and small-for-gestational-age infants in low- and middle-income countries: a pooled country analysis. Lancet. 2013 August 3, 382(9890), 417-425.

Surkan P, Kiihl S, **Kozuki N**, Carvalho-Vieira L. Social support of low-income Brazilian mothers related to time to completion of childhood vaccination. Hum Vaccin Immunother. 2012 May 1;8(5):596-603. Epub 2012 May 1.

Kozuki N, Lee AC, Katz J. Moderate to Severe, but Not Mild, Maternal Anemia, is Associated with Increased Risk of Small-for-Gestational-Age Outcomes. J Nutr. 2012 Feb;142(2):358-362. Epub 2011 Dec 21.

Under review

Kozuki N, Katz J, Khatry SK, Tielsch JM, LeClerq SC, Mullany LC. Awareness and utilization of obstetric ultrasonography in rural Sarlahi District, Nepal: a community-based survey. Under review (International Journal of Gynecology and Obstetrics).

Kozuki N, Katz J, Khatry SK, Tielsch JM, LeClerq SC, Mullany LC. Association between non-cephalic presentation / multiple gestation and intrapartum-related adverse outcomes in rural Nepal. Under review (Pediatrics).

Kozuki N, Katz J, Kennedy C, Khatry SK, Tielsch JM, LeClerq SC, Mullany LC. Perceptions and care seeking pertaining to non-cephalic births in rural Sarlahi District, Nepal. Under review (Qualitative Health Research).

Book chapter

Kozuki N, Lee AC, Black RE, Katz J. Nutritional and reproductive risk factors for small-for-gestational-age and preterm births. Embleton ND, Katz J, Ziegler EE (eds): Low-Birthweight Baby: Born Too Soon or Too Small. Nestlé Nutr Inst Workshop Ser, vol 81, 2015.

Katz J, Lee AC, **Kozuki N**, Black RE. Mortality risk among term and preterm small for gestational age infants. Embleton ND, Katz J, Ziegler EE (eds): Low-Birthweight Baby: Born Too Soon or Too Small. Nestlé Nutr Inst Workshop Ser, vol 81, 2015.

Report contribution

Naik, R. and R. Smith. Impacts of Family Planning on Nutrition. Washington, DC: Futures Group, Health Policy Project. 2015.

Inter-agency standing committee Reference Group for Mental Health and Psychosocial Support in Emergency Settings. Nepal Earthquakes 2015: Desk Review of Existing Information with Relevance to Mental Health and Psychosocial Support. May 2015.

Peer review activity
American Journal of Public Health
BMC Pediatrics
BMC Pregnancy and Childbirth
BMC Public Health
Paediatric and Perinatal Epidemiology
Pediatrics

CONFERENCE / SEMINAR PRESENTATIONS

Kozuki N, Lee AC, Katz J. Maternal nutritional and reproductive health risk factors for small-for-gestational-age and preterm births. Oral presentation at the 81st Nestlé Nutrition Institute Workshop (April 2014), Magaliesburg, South Africa.

Kozuki N, Walker N. Association between Short/Long Preceding Birth Intervals and Child Mortality: Reference Birth Interval Children of the Same Mother as Comparison. Oral presentation at Pediatric Academic Societies Annual Meeting (May 2013), Washington, DC.

Kozuki N, Lee AC, Silveira M, et al. The Association of Parity and Maternal Age with Small−for−Gestational−Age, Preterm, and Neonatal and Infant Mortality. Poster presentation at Pediatric Academic Societies Annual Meeting (May 2013), Washington, DC.

Kozuki N, Sonneveldt E, Walker N. Testing the Parity Effect: Do background differences between high fertility and low fertility mothers explain the association between high parity and child mortality? Poster presentation at Consortium of Universities for Global Health Conference (March 2013), Washington, DC.

Kozuki N, Lee AC, Katz J. Reproductive health risk factors for small-for-gestational-age and preterm births. Oral presentation at Child Health Epidemiology Reference Group biannual meeting (June 2012), Geneva, Switzerland.

Kozuki N, Lee AC, Katz J. Reproductive health risk factors for small-for-gestational-age and preterm births. Oral presentation at Child Health Epidemiology Reference Group Activity 8 meeting (May 2012), London, UK.

Kozuki N, Walker N. Exploration of parity, maternal age, and birth interval as risk factors for adverse neonatal, infant, and child outcomes. Oral presentation at Lives Saved Tool (LiST) Reproductive Health Research meeting (April 2012), Baltimore, USA.

PROFESSIONAL DEVELOPMENT

Language: Japanese – native, Mandarin – highly proficient, Nepali – conversational
Computer Skills: Stata, Atlas.ti, Endnote, Refworks
Volunteering:

- English-as-a-Second-Language teaching volunteer – Esperanza Center, Baltimore, MD (Sep 2011 -Sep 2013)
- Mentor for high school student - Incentive Mentoring Program, Baltimore, MD (Sep 2011 – Dec 2012)